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(54) SYSTEM FOR DELIVERING AN ANVIL ASSEMBLY TO A SURGICAL SITE

(57) An anvil assembly delivery system includes an anvil assembly having a center rod and an anvil head assembly pivotally secured to the center rod a flexible tube having a first end configured for oral insertion into a patient and a second end engaged with the anvil assembly, and a retrieval suture connected to the head assembly positioned to extend from the anvil assembly in a direction opposite to the flexible tube. The anvil assembly delivery system also includes a spacer suture tube positioned adjacent the anvil head assembly and defining a suture channel, which is supported on the retrieval suture and is dimensioned to prevent the retrieval suture from becoming trapped in the staple line of a stapling device. In an embodiment, the spacer is a suture tube defining a suture channel which receives the retrieval suture.

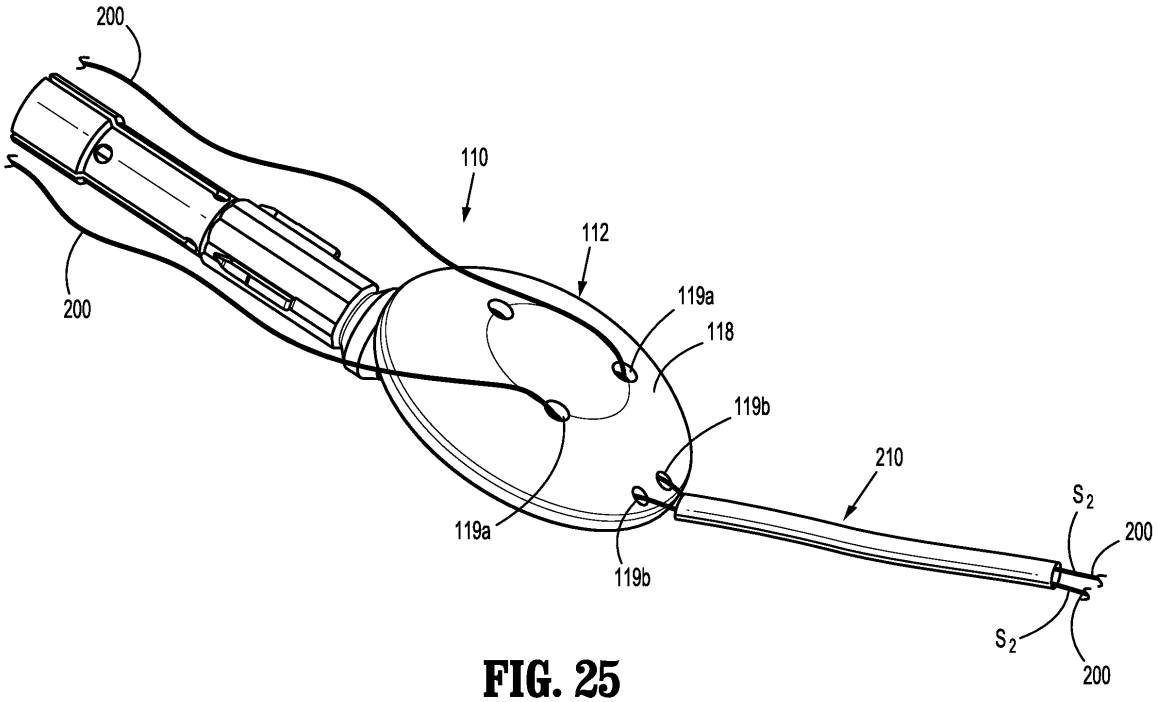

FIG. 25

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Description

Technical Field

[0001] The present disclosure relates generally to a system for delivering an anvil assembly to a surgical site. More specifically, the present disclosure relates to a system for delivering an anvil assembly to a surgical site including a retrieval suture and guide tube.

Background

[0002] Surgical anastomosis procedures using a circular stapler often require trans-oral delivery of an anvil assembly to a surgical site. In known procedures, a suture can be attached to the anvil assembly to facilitate retrieval of the anvil assembly from the surgical site after completion of a stapling operation. During such procedures, complications can result if the retrieval suture becomes trapped in the staple line.

SUMMARY

[0003] An anvil assembly delivery system is provided which includes an anvil assembly including a center rod and an anvil head assembly secured to the center rod, and a flexible tube having a first end configured for oral insertion into a patient and a second end. The anvil assembly is connected to the second end of the flexible tube. A retrieval suture is connected to the head assembly and is positioned to extend from the anvil assembly in a direction opposite to the flexible tube. A spacer is supported on the retrieval suture adjacent the anvil head assembly. The spacer is dimensioned to prevent the suture from being clamped between the anvil head assembly and a stapling instrument and becoming trapped in a staple line.

[0004] In embodiments, the spacer includes a suture tube defining a suture channel and the retrieval suture extends through the suture channel.

[0005] In certain embodiments, the anvil head assembly is movable from a first tilted position to a non-tilted operative position.

[0006] In certain embodiments, the suture tube has an outer diameter or thickness of between 0.0625 inches and 0.50 inches. In other embodiments, the suture tube has an outer diameter or thickness of between 0.0625 inches and 0.25 inches. In some embodiments, the suture tube has an outer diameter or thickness of about .25 inches.

[0007] In embodiments, a tensioning member is connected to the anvil head assembly to maintain the anvil head assembly in the first tilted position.

[0008] In certain embodiments, the anvil head assembly defines first openings and the tensioning member includes a first suture. The first suture extends through the first openings and into an opening in the flexible tube.

[0009] In embodiments, the anvil head assembly is pivotal from the operative non-tilted position to a second tilted position which is different than the first tilted position.

[0010] In certain embodiments, the anvil assembly further comprises a rotatable cam member and a plunger. The plunger is spring biased into contact with the cam member and movable distally to rotate the cam member to effect movement of the anvil head assembly from the first tilted position to the operative non-tilted position.

[0011] In embodiments, the cam member is rotatable and the plunger is movable distally to move the anvil head assembly from the operative tilted position to a second tilted position different than the first tilted position.

[0012] In certain embodiments, an adapter is provided to connect the anvil assembly to the second end of the flexible tube.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] Various embodiments of the presently disclosed tilt anvil assembly are disclosed herein with reference to the drawings wherein:

FIG. 1 is a perspective view of a surgical stapling device including an embodiment of an anvil assembly according to the present disclosure;

FIG. 2 is a first perspective side view of the anvil assembly of FIG. 1 in the non-tilted position;

FIG. 3 is a second perspective side view of the anvil assembly shown in FIGS. 1 and 2;

FIG. 4 is an exploded side view of the anvil assembly of FIGS. 1-3;

FIG. 5 is an end view of the anvil assembly of FIGS. 1-3;

FIG. 6 is a cross-sectional side view of a distal end of the tilt anvil assembly of FIGS. 1-4 taken along line 6-6 of FIG. 5 and showing the head assembly in the non-tilted operative position;

FIG. 7 is a cross-sectional side view of a distal end of the anvil assembly of FIGS. 1-6 taken along line 7-7 of FIG. 5 and showing the head assembly in the non-tilted operative position;

FIG. 8 is an enlarged side view of the cam latch member of the anvil assembly of FIGS. 1-4;

FIG. 9 is a top view of the anvil assembly of FIGS. 1-4 supported on an anvil delivery system;

FIG. 10 is an enlarged exploded view of the anvil delivery system of FIG. 9;

FIG. 11 an enlarged top view of the anvil delivery system of FIGS. 9 and 10, including the anvil assembly of FIGS. 1-4 shown in the first tilted position tensioned by the suture;

FIG. 12 is a cross-sectional side view of the anvil assembly and anvil delivery system of FIG. 11 taken along lines 12-12 of FIG. 11;

FIG. 13 is a cross sectional side view (showing the area of detail of FIG 12) of the anvil assembly of FIGS. 1-4, in a pre-fired tilted position supported on

the anvil delivery system of FIG. 9;
FIG. 14 is an enlarged view of portion 14 of FIG. 13;
FIG. 15 is an illustration of the surgical stapling instrument of FIG. 1 and the anvil delivery system of FIG. 9 with the anvil delivery system inserted trans-orally into a patient and the stapling instrument inserted through an incision in the stomach;
FIG. 16 is an enlarged side view of the distal head portion of the surgical stapling device of FIGS. 1 and 15;
FIG. 17 is an enlarged side view of the distal head portion of the surgical stapling device of FIGS. 1 and 15, showing the anvil assembly of FIGS. 1-4 received thereon.
FIG. 18 is an enlarged cross-sectional side view of the distal head portion of the surgical stapling device of FIG. 1, including the connected anvil assembly of FIGS. 1-4 shown in an approximated pre-fired non-tilted operative position;
FIG. 19 is an enlarged cross-sectional side view of the distal head portion of the surgical stapling device of FIG. 1, including the connected anvil assembly of FIGS. 1-4 shown in a post-fired non-tilted operative position;
FIG. 20 is an enlarged cross-sectional side view of the distal end of the anvil assembly of FIGS 1-4 in the post-fired non-tilted operative position corresponding to the position of FIG. 19;
FIG. 21 is an enlarged cross-sectional side view of the distal end of the anvil assembly of FIGS. 1-4 in a post-fired second tilted position;
FIG. 22 is a cross-sectional side view of the anvil assembly of FIGS. 1-4 in a post-fired second tilted position (corresponding to the position of FIG. 21) shown supported on an anvil retainer of the surgical stapling device of FIG. 1;
FIG. 22A is another cross-sectional side view of the anvil assembly of FIGS 1-4 corresponding to the anvil assembly position of FIG. 22;
FIG. 23 is an enlarged view showing the designated area of detail of FIG. 22A;
FIG. 24 is a side view of the anvil assembly of FIG. 22 supported on the anvil retainer of the surgical stapling device of FIG. 1;
FIG. 25 is a side, perspective view of the anvil assembly including a proximal suture tube;
FIG. 26 is an illustration of the surgical stapling instrument of FIG. 1 and the anvil delivery system of FIG. 9 with the anvil delivery system, including the proximal suture tube of FIG. 25, inserted trans-orally into a patient and the stapling instrument inserted through an incision in the stomach; and
FIG. 27 is an enlarged view of the indicated area of detail shown in FIG. 26.

DETAILED DESCRIPTION OF EMBODIMENTS

[0014] Embodiments of the presently disclosed anvil assembly will now be described in detail with reference to the drawings in which like reference numerals designate identical or corresponding elements in each of the several views. Throughout this description, the term "proximal" will refer to the portion of the instrument closer to the operator and the term "distal" will refer to the portion of the instrument further from the operator.

[0015] FIG. 1 illustrates an embodiment of a surgical stapling device configured for use with a tilt anvil assembly according to the present disclosure. Briefly, surgical stapling device 10 includes a proximal handle assembly 12, an elongated central body portion 14 including a curved elongated outer tube 14a, and a distal head portion 16. The length, shape and/or the diameter of body portion 14 and distal head portion 16 may also be varied to suit a particular surgical procedure.

[0016] With reference still to FIG. 1, handle assembly 12 includes a stationary handle 18, a firing trigger 20, a rotatable approximation knob 22 and an indicator 24. A pivotally mounted trigger lock 26 is fastened to handle assembly 12 and is manually positioned to prevent inadvertent firing of stapling device 10. Indicator 24 is positioned on the stationary handle 18 and includes indicia, e.g., color coding, alpha-numeric labeling, etc., to identify to a surgeon whether the device is approximated and is ready to be fired. Head portion 16 includes an anvil assembly 110 and a shell assembly 31. A more detailed discussion of surgical stapler 10 is disclosed in U.S. Pat. Nos. 7,364,060 and 7,303,106, the contents of which are incorporated herein by reference in its entirety.

[0017] Referring now to FIGS. 2-7, an embodiment of the anvil assembly of the present disclosure is shown generally as reference numeral 110. Anvil assembly 110 is shown in a non-tilted or operative position wherein the staple deforming pockets 130 face the staple slots of the instrument. Anvil assembly 110 includes a head assembly 112 and a center rod assembly 114. Head assembly 112 includes a post 116, a housing 118, a backup member or plate 120, a cutting ring 122, a cutting ring cover 123, an anvil plate 124, a spacer or washer 125, a cam latch member 126, and a retainer member 127. Post 116 is monolithically formed with and centrally positioned within housing 118. Alternately, housing 118 and post 116 may be formed separately and fastened together using a known fastening technique, e.g., welding.

[0018] As will be discussed in further detail below, housing 118 includes openings 119a, 119b sized and dimensioned to receive one or more sutures or tensioning members "S". During use, a first suture "S_1" (FIG. 11) is inserted through openings 119a and is used to retain head assembly 112 in a retracted or first tilted position (FIGS. 11 and 12) during insertion of anvil assembly 110 within a patient. That is, suture "S_1" operates as a tensioning member to maintain the head assembly in the first tilted position. A second suture "S_2" is inserted through openings 119b and is configured to permit retrieval of tilt anvil assembly 110 from within a patient if desired. During trans-oral insertion of anvil assembly

110, suture "S2" extends from the mouth of patient, permitting the anvil assembly 110 to be retrieved trans-orally. As shown, second suture "S_2" extends in a direction opposite the direction of suture "S_1".

[0019] With reference still to FIGS. 2-7, anvil plate 124 is supported in an outer annular recess 128 of housing 118 and includes a plurality of staple deforming pockets 130 for receiving and deforming staples. At least one tab 124a extends radially outwardly from anvil plate 124 and is received within a cutout 132 formed in an outer rim of housing 118. Tab 124a and cutout 132 function to align or properly position anvil plate 124 within annular recess 128 of housing 118.

[0020] With particular reference to FIGS. 4, 6 and 7, head assembly 112 will be described in detail. Backup plate 120 includes a central opening 134 which is positioned about post 116 within an inner annular recess 136 of housing 118 between post 116 and outer annular recess 128. Backup plate 120 includes a raised platform 120a. Cutting ring 122 includes an opening 122a having a configuration substantially the same as platform 120a. Although platform 120a is illustrated as having a circular shape, other configurations are envisioned, e.g., square, rectangular, triangular, etc. In one embodiment, cutting ring 122 is formed from polyethylene and is fixedly secured to backup plate 120 using, for example, an adhesive, to form a backup plate/cutting ring assembly. Backup plate 120 is formed from a hard material, e.g., a metal. Alternately other materials of construction may be used to construct backup plate 120 and cutting ring 122. Further, backup plate 120 and cutting ring 122, in the alternative, can be formed as a single or unitary structure.

[0021] Still referring to FIGS. 6 and 7, a cutting ring cover 123 is secured to an outwardly facing or proximal surface of cutting ring 122 using, for example, an adhesive. In one embodiment, cutting ring cover 123 is formed from a material or materials, which have a hardness greater than that of the cutting ring, e.g., mylar. In one embodiment, cutting ring cover 123 includes two layers of mylar (not shown) which are joined together using an adhesive and a polypropylene coating. Alternately, cutting ring 122 need not have a cover. Cutting ring 122 and backup plate 120 are slidably mounted about post 116. Backup plate 120 includes a pair of inwardly extending fingers 138 which will be described in further detail below.

[0022] With reference still to FIGS. 4, 6 and 7, retainer member 127 is positioned in inner annular recess 136 between backup plate 120 and a back wall 118a of housing 118. In one embodiment, retainer member 127 is annular and includes a plurality of deformable tabs 127a which engage a rear surface of backup plate 120. Retainer member 127 prevents backup plate 120 and cutting ring 122 from moving or being pushed into inner annular recess 136 of housing 118 until a predetermined force sufficient to deform tabs 127a has been applied to the backup plate/cutting ring assembly. The predetermined force can be close to but is less than the force applied by an annular cutting blade of a surgical stapling device when it engages, for example, the cutting ring of anvil assembly 110. In one embodiment by way of example, the predetermined force is between about ten pounds and about ninety pounds and can be about thirty (30) pounds. When the predetermined force is reached, e.g., during cutting of tissue, backup plate 120 is urged into inner annular recess 136 and compresses retainer member 127. It is envisioned that other crushable, deformable, collapsible or movement restricting members may be used to retain the backup plate/cutting ring assembly in a fixed position until a predetermined force has been applied to the backup plate/cutting ring assembly.

[0023] As illustrated in FIG. 4, anvil center rod assembly 114 includes a center rod 152, a plunger 154 and plunger spring 156. A first end of center rod 152 includes a pair of arms 159 which define a cavity 159a. Each arm 159 has a transverse through bore 158 which is aligned with a central longitudinal axis of center rod 152. Alternately, through bores 158 can be offset from the longitudinal axis of center rod 152. Post 116 of anvil head assembly 112 is dimensioned to be positioned within cavity 159a and also includes a transverse through bore (not shown). A pivot member 162 pivotally secures post 116 to center rod 152 via the through bores such that anvil head assembly 112 may be pivotally mounted to anvil center rod assembly 114.

[0024] Turning briefly to FIG. 8, cam latch member 126 includes a body 126a having a through bore 126b. Through bore 126b is dimensioned to receive pivot member 162 such that cam latch member 126 is pivotally mounted within transverse slot 172 (FIG. 3) of post 116 about pivot member 162. Referring now to FIGS. 3, 6 and 7, cam latch member 126 includes a first body portion 126c which extends partially from slot 172 of post 116 and is positioned to be engaged by a finger 166 of plunger 154. First body portion 126c is configured such that the distance between the surface of first body portion 126c and through bore 126b increase in a clockwise direction about cam latch member 126. In this manner, plunger 154 is able to move forward as cam latch member 126 rotates in a clockwise direction. Additionally, this configuration of first body portion 126c permits plunger 154 to be retracted as cam latch member rotates in a counterclockwise direction. Cam latch member 126 also includes an edge 126f, including a tab 126g. A leading portion of edge 126f is configured to be urged into engagement with an inner periphery 120b of backup plate 120 by an engagement finger 166 of plunger 154 when anvil head 112 is in its non-tilted or operative position. Tab 126g is configured to engage backwall 118a of housing 118 to prevent cam latch member 126 from rotating counterclockwise relative to housing 118.

[0025] With reference to FIG. 6, plunger 154 is slidably positioned in a bore 164 formed in the first end of center rod 152. Plunger 154 includes an engagement finger 166 which is offset from the pivot axis of anvil head assembly 112 and biased into engagement with edge 126c of cam latch 126. Engagement of finger 166 with edge 126c of

cam latch 126 presses a leading portion of edge 126f against an inner periphery of back plate 120 to urge anvil head assembly 112 to an operative or non-tilted position on center rod 152. In this non-tilted position, finger 166 remains spaced proximally from post 116 of anvil assembly 110.

[0026] Turning to FIG. 7, in the pre-fired operative position of head assembly 112, i.e. when head assembly 112 has been pivoted to its non-tilted position, fingers 138 formed on backup plate 120 engage protrusions 152b adjacent top surface 152a of center rod 152 to prevent head assembly 112 from pivoting about pivot member 162.

[0027] Anvil head assembly 112 may be tilted α degrees (FIG. 13) relative to anvil center rod assembly 114 to the pre-fired first tilted position by the suture "S_1" as described below for insertion. In one embodiment, anvil head assembly 112 is tilted less than ninety degrees and preferably about seventy degrees (70°) in its pre-fired tilted position; however it should be understood that tilting head assembly 112 to other degrees is also contemplated. Tilting of anvil head assembly 112 relative to anvil center rod assembly 114 by the suture S1 causes cam latch member 126 positioned within the inner periphery of the backup plate 120 to rotate, causing body portion 126c of cam latch member 126 to engage finger 166 of plunger 154. As cam latch assembly 126 rotates counterclockwise (as viewed in FIG. 14) with the tilting of anvil head assembly 112, plunger 154 is retracted within bore 164 of anvil center rod assembly 114, thereby compressing spring 156. In this manner, finger 166 of plunger 154 is distally biased against body portion 126c of cam latch member 126.

[0028] With reference to FIGS. 3 and 4, a second end of center rod 152 includes a bore 180 defined by a plurality of flexible arms 182. Flexible arms 182 each include an opening 182a dimensioned to receive a projection formed on or connected to a shell assembly 31 (FIG. 18). Alternatively, openings 182a may be configured to receive a suture for permitting retrieval of anvil assembly 110. The proximal ends of each of the flexible arms 182 include an internal shoulder 184 dimensioned to releasably engage shell assembly 31 of surgical stapling device 10 to secure anvil assembly 110 to the surgical stapling device. A plurality of splines 186 are formed about center rod 152. Splines 186 function to align anvil assembly 110 with the staple holding portion of a surgical stapling device. Center rod 152 also includes an annular recessed portion 190 to facilitate grasping of anvil assembly 110 by a surgeon with a grasper. Recessed portion 190 may include a roughened or knurled surface or an overmold to facilitate grasping of anvil assembly 110.

[0029] With reference now to FIGS. 9-12, a system for delivering anvil assembly 110 within a patient is shown generally as anvil delivery system 50. Anvil delivery system 50 includes a flexible tube 52 and an adapter 62. Flexible tube 52 includes an open end 52a. Adapter 62 and anvil assembly 110 are supported on open end 52a of flexible tube 52. Open end 52a of flexible tube 52 includes a through bore 53 extending therethrough configured to receive a locking pin 54. In embodiments, locking pin 54 can be omitted. Open end 52a further includes an opening 55, used for alignment of the printing on the tube 50 during manufacture. Closed end 52b of flexible tube 52 is configured for trans-oral insertion in a patient. Flexible tube 52 may include markings or other gradations 56 along the length thereof to indicate to a surgeon how much of flexible tube 52 has been received within the patient during insertion and/or to indicate the length of flexible tube 52 remaining in the patient during removal.

[0030] With particular reference to FIG. 10, adapter 62 includes a first end 62a configured to be received within open end 52a of flexible tube 52 and a second end 62b configured to be received within bore 180 formed in center rod 152 of anvil assembly 110. First end 62a includes a series of annular rings 64 configured to frictionally retain first end 62a of adapter 62 within open end 52a of flexible tube 52. Second end 62b of adapter 62 includes a longitudinal guide member 66 configured to be received between flexible arms 182 formed in center rod 152 of anvil assembly 110. In addition, second end 62b of adapter 62 is sized to allow center rod 152 of anvil assembly 110 to freely slide into and off second end 62b of adapter 62. Adapter 62 further includes a first through bore 70 formed in a central hub portion 62c as well as second and third through bores 72, 74 formed in first end 62a. Through bore 72 is configured to align with through bore 53 formed in open end 52a of flexible tube 52 and is sized to receive locking pin 54. As discussed above, in embodiments the locking pin 54 can be omitted. As such bore 72 can be omitted and adapter 62 can be secured to flexible tube 52 via frictional engagement between rings 64 and an inner surface of the tube 52. Bore 74 is configured to receive both ends of the suture S1. Bore 70 can also receive the suture ends to enhance retention.

[0031] With particular reference now to FIGS. 10-14, anvil assembly 110 is supported on anvil delivery system 50. Securing anvil assembly 110 to anvil delivery system 50 requires that suture "S_1" is thread through openings 119a (shown also in FIG. 2) formed on anvil head 112 such that first and second ends of suture "S_1" are positioned on different sides of center rod 152. Second end 62b of adapter 62 is positioned within through bore 180 of center rod 152 such that longitudinal guide 66 is received between two of arm members 182. Each of the first and second ends of suture "S_1" is inserted through bore 74 (FIG. 10) formed in adapter 64 and through open end 52a of flexible member 52. Anvil head 112 is then rotated to a first tilted position as first and second ends of suture "S_1" are pulled through opening 74, applying tension on the anvil head forcing it to pivot counterclockwise as viewed in the orientation of FIG. 13. Such pivoting forces plunger 154 proximally as described above.

[0032] First end 62a of adapter 62 is inserted into open end 52a of flexible member 52. The frictional contact between annular rings 64 of first end 62a of adapter 62 and

an inner surface of flexible tube 52 secures adapter 62 to flexible tube 52 and prevents suture "S_1" from loosening as it is clinched between the outer wall of the adapter 62 and inner wall of flexible tube 52. It is envisioned that more than one suture may be used to secure anvil head assembly 112 in a pre-fired tilted position. It is also envisioned that the suture S_1 need not be passed through bore 74 but instead is just clamped between the adapter 62 and the inner wall of the flexible tube 52.

[0033] With reference also to FIG. 15, a method for delivering anvil assembly 110 to a surgical site within a patient will be described. In one method, anvil assembly 110 is provided in the first tilted position supported on anvil delivery system 50 and ready for delivery. Alternatively, a clinician secures anvil assembly 110 to anvil delivery system 50 as discussed above. With anvil assembly 110 secured to flexible tube 52, the surgeon inserts closed end 52b of flexible tube 52 in the patient's mouth "M" and moves closed end 52b along with flexible tube 52 down through esophagus "E" to a surgical site, i.e., the stomach "St".

[0034] After insertion, the surgeon then makes a first incision "I_1" at the surgical site (stomach "St" as shown) to create an inner access to closed end 52b of flexible tube 52 and then pulls closed end 52b of flexible tube 52 through first incision "I_1". In some procedures it may be beneficial to pull flexible tube 52 through incision "I_1" until center rod 152 of anvil assembly 110 advances through first incision "I_1". When anvil assembly 110 is properly positioned at the surgical site, the surgeon releases anvil delivery system 50 from anvil assembly 110 by cutting suture "S_1" and separating anvil assembly 110 from second end 62b of adapter 62. Flexible tube 52 (with fitting 62) may then be pulled from the body through first incision "I_1".

[0035] Severing of suture "S_1" permits plunger 154 (FIG. 13) to extend from within bore 164 (FIG. 6), thereby causing finger 166 to engage body portion 126c of cam latch member 126. Rotation of cam latch member 126 (clockwise as viewed in the orientation of FIG. 14) causes edge 126f of latch member 126, engaged with the inner periphery of backup plate 120, to urge anvil head assembly 112 to return to a non-tilted operative position (e.g. the position of FIG.6). Additionally, the distal end of stapling device 10 may be configured to engage finger 166 of plunger 154 as anvil assembly 110 is attached to surgical stapling device 10. In this manner, the distal end of surgical stapling device 10 urges plunger 154 distally, thereby ensuring the rotation of cam latch 126 and anvil head assembly 112 to a non-tilted position.

[0036] With particular reference to FIG. 15, in one method, a second incision "I_2" is then formed at the surgical site such that distal head portion 16 of surgical stapling device 10 may be received therethrough. Alternatively, distal head portion 16 of surgical stapling device 10 may be received through first incision "I_1" once anvil delivery system 50 has been removed therefrom.

[0037] Turning briefly to FIGS. 16 and 17, anvil assembly 110 is operably received on an anvil retainer 32 extending from shell assembly 31 formed on a distal end of surgical stapling device 10. Once anvil assembly 110 is received on surgical stapling device 10, surgical stapling device 10 operates in the manner discussed in U.S. Pat. No. 7,364,060, previously incorporated herein in its entirety by reference. Note that alternatively, suture S1 can be severed after the distal head portion 16 of the stapling device 10 receives the anvil assembly 110. After attachment, the rotation knob 22 is rotated to approximate the anvil assembly 110 and distal head portion 16 to clamp tissue therebetween, and then the firing trigger is actuated to fires the staples as disclosed in U.S. Pat. No. 7,364,060.

[0038] The operation of anvil assembly 110 will now be described with reference to FIGS. 18-23. When anvil assembly 110 is in its pre-fired non-tilted position (e.g. FIG. 18), backup plate 120 is spaced from backwall 118a of housing 118 by retainer 127 and protrusions 152b of center rod 152 engage fingers 138 of backup plate 120 (also shown in FIGS. 6 and 7) to prevent tilting of anvil head assembly 112 about pivot member 162. Finger 166 of plunger 154 is urged by spring 156 into engagement with body portion 126c of cam latch member 126 to urge cam latch member 126 in a clockwise direction (as viewed in FIG. 18), about pivot member 162 such that edge 126f of cam latch member 126 engages inner periphery 120b of backup member 120.

[0039] The firing of surgical stapling device 10 causes a knife blade 33 thereof to engage cutting ring 122 to move cutting ring 122 and backup plate 120 into annular recess 136 of housing 118 of anvil head assembly 112. Arrows "W" in FIG. 19 indicate how cutting ring 122 and backup plate 120 move as a result of the firing of surgical stapling device 10. When such movement occurs, deformable tabs 127a of retainer 127 (labeled in FIGS. 6 and 7) are deformed against backwall 118a of housing 118 and fingers 138 of backup member 120 move away from protrusions 152b of center rod 152. Further, inner periphery 120b of backup plate 120 moves past edge 126f of cam latch member 126 such that cam latch member 126 is urged to pivot about pivot member 162 (clockwise as viewed in the orientation of FIG. 21) in the direction indicated by arrow "X" in FIGS. 21 and 22 by plunger 154 (spring biased distally) to a position in which body portion 126e of cam latch 126 is positioned in front of and engages backup plate 120. Engagement of plunger 154 with cam latch member 126 urges cam member 126 to further rotate clockwise which due to its configuration enables spring biased plunger 154 to move further distally so angled surface 167 of plunger 154 contacts the surface of post 116 of anvil head assembly 112 to move the anvil head assembly 118 to a second tilted position (FIGS. 22A and 23). It is noted that anvil head assembly 112 will not immediately tilt to its second tilted position upon firing of surgical stapling device 10 because, upon firing, anvil head assembly 112 is in an approximated position, i.e., the anvil head assembly 112 is in close

alignment with shell assembly 31 of stapling device 10, and, therefore, does not provide room for head assembly 112 to pivot. As such, the anvil head assembly 112 will only begin to tilt when anvil assembly 110 and shell assembly 31 of surgical stapling device 10 are being unapproximated and there is a sufficient gap between the anvil assembly 110 and the distal head portion 16 of the stapling device 10.

[0040] As anvil head assembly 112 pivots towards its forward or second tilted position, finger 166 of plunger 154 maintains surface 126e of cam latch member 126 in contact with backup plate 120 to prevent backup plate 120 from sticking to the knife blade as the knife blade is retracted. It is noted that curved surface 126e of cam latch member is configured to eliminate any gap and ensure contact between surface 126e of cam latch member 126 and backup plate 120 to hold backup plate 120 in place during and after the knife blade is retracted such that the cutting ring and backup plate assembly stay in their correct position during continued tilting of anvil assembly 112. Anvil assembly 110 is configured such that anvil head assembly tilts to a forward or second tilted position 13 degrees (FIG. 24) relative to center rod assembly 114. As can be appreciated, the anvil head assembly therefore pivots in a first direction from an initial (first) tilted position to an untilted operative position for application of staples. After firing of the instrument, the anvil head pivots in the same direction to a second tilted position. In one embodiment, anvil head assembly 112 is tilted less than ninety degrees and preferably about seventy degrees (70°) to its second tilted position such that the total pivoting movement of the anvil from the retracted or first tilted position to the forward or second tilted position is about one-hundred and forty degrees (140°). It should however be noted that the tilting of anvil head assembly 112 to other degrees for the first and/or second tilted position is also contemplated.

[0041] FIGS. 25-27 illustrate an alternate embodiment of the anvil assembly delivery system shown generally as 50' (FIG. 26). Anvil assembly delivery system 50' is substantially identical to anvil delivery system 50 but further includes a spacer supported on the second or retrieval suture "S_2". The spacer is dimensioned to prevent the retrieval suture "S_2" from being clamped between the anvil head assembly 112 and a stapling device 10 (FIG. 1) and becoming trapped in a staple line when the stapling device 10 is fired. In one embodiment, the spacer includes a suture tube 210 which will be discussed in further detail below. It is also envisioned that the spacer may comprise any structure which can be supported on the suture "S_2" to prevent approximation of the anvil head assembly 112 and the stapling device 10 to a degree to enable firing as will be discussed below.

[0042] Known stapling devices have lockouts which prevent the surgical stapling device from being fired until the anvil assembly and the shell assembly of the surgical stapling device have been closely approximated into a firing zone. See, e.g., U.S. Patent No. 7,364,060. Providing a lockout to lock the stapling device to prevent firing of the stapling device until the anvil head assembly and stapling device are approximated into the firing zone ensures that staples ejected from the shell assembly are close enough to contact the anvil assembly 112 and be properly formed by the anvil assembly 112 when fired from the stapling device 10.

[0043] In the anvil delivery system 50', the spacer, e.g., suture tube 210, is supported on the suture "S_2" adjacent the anvil head assembly 112. The suture tube 210 has a thickness or configuration to prevent approximation of the anvil assembly and shell assembly into the firing zone when the spacer 210 is positioned between the anvil assembly and the shell assembly. As such, when the suture "S_2" and, thus, the suture tube 210, is inadvertently clamped between the anvil head assembly 112 and the stapling device 10, the anvil head assembly 112 is prevented from being approximated in relation to the stapling device 10 into the firing zone to prevent firing of the stapling device 10. This ensures that the retrieval suture "S_2" will not become trapped in the staple line when the stapling device 10 is fired.

[0044] As discussed above, the retrieval suture "S_2" is positioned through the openings 119b (FIG. 25) formed in the housing 118 of the head assembly 112 of the anvil assembly 110. The ends 200 of the suture "S_2" extend from the mouth "M" of the patient "P". In one embodiment, the ends 200 extend through a suture tube 210 and are connected to a reel assembly 202 which is configured to house and manipulate the retrieval suture "S_2" during delivery of the anvil assembly 110 to the surgical site. Such a reel assembly is disclosed in U.S. Application Serial No. 14/078,766 which is incorporated herein by reference in its entirety.

[0045] In use, the suture "S_2" is secured to the anvil assembly 110 during delivery of the anvil assembly 110 to a surgical site and during operation of the stapling device 10. As illustrated, the proximal suture tube 210 defines a suture channel 212 that receives the suture "S_2". The proximal suture tube "S_2" is positioned adjacent to the head assembly 112 and functions to prevent the suture "S_2" from being clamped between the anvil assembly 110 and the stapling device 10 and getting caught in the staple line as discussed above. More specifically, when the proximal suture tube 210 is positioned between the anvil assembly 110 and the stapling device 10, the proximal suture tube 210 has a thickness which prevents approximation of the anvil assembly 110 and the stapling device 10 into the firing zone. As such, when the suture tube 210 is clamped between the anvil assembly 110 and the stapling device 10, the stapling device 10 will be locked out and cannot be fired. In embodiments, the proximal suture tube 210 has an outer diameter or thickness of between 0.0625 inches and 0.50 inches. In other embodiments, the proximal suture tube 210 has an outer diameter or thickness of between 0.0625 inches and 0.25 inches. In some embodiments, the suture tube has an outer diameter or thickness of about .25 inches. Alterna-

tively, the suture tube 210 can have any thickness or configuration which prevents the surgical stapling device 10 and anvil assembly from being approximated to within the firing zone.

[0046] It is noted that, in certain embodiments, the suture tube 210 may extend the full distance, or a substantial portion of the distance, from the anvil assembly to a position externally of a patient's mouth. In addition to preventing the retrieval suture from becoming trapped in the suture line, such an elongated suture tube 210 also functions to maintain the cleanliness of the suture and prevent contaminants on the suture from contacting the anastomosis during withdrawal of the suture from the surgical site.

[0047] It will be understood that various modifications may be made to the embodiments disclosed herein. For example, the suture tube 210 need not be tubular but rather can include any structure or configuration attachable to the suture S_2 capable of preventing approximation of the stapling device and the anvil assembly into the firing zone. Therefore, the above description should not be construed as limiting, but merely as exemplifications of preferred embodiments. Those skilled in the art will envision other modifications within the scope and spirit of the claims appended hereto.

[0048] The invention may be described by reference to the following numbered paragraphs:-

1. An anvil assembly delivery system comprising:

   an anvil assembly including a center rod and an anvil head assembly secured to the center rod;
   a flexible tube having a first end configured for oral insertion into a patient and a second end, the anvil assembly being connected to the second end of the flexible tube;
   a retrieval suture connected to the head assembly, the retrieval suture being positioned to extend from the anvil assembly in a direction opposite to the flexible tube; and
   a spacer supported on the retrieval suture adjacent the anvil head assembly, the spacer being dimensioned to prevent the suture from being clamped between the anvil head assembly and a stapling instrument and becoming trapped in a staple line.

2. The anvil assembly delivery system according to claim 1, wherein the spacer includes a suture tube defining a suture channel, the suture channel receiving the retrieval suture and being positioned adjacent the anvil head assembly.

3. The anvil assembly delivery system according to paragraph 2, wherein the anvil head assembly is movable from a first tilted position to a non-tilted operative position.

4. The anvil assembly delivery system according to paragraph 2, wherein the suture tube has an outer diameter of between 0.0625 inches and 0.50 inches.

5. The anvil assembly delivery system according to paragraph 4, wherein the suture tube has an outer diameter of between 00.625 inches and 0.25 inches.

6. The anvil delivery system according to paragraph 4, wherein the suture tube has an outer diameter of .25 inches.

7. The anvil assembly delivery system according to paragraph 3, further including a tensioning member connected to the anvil head assembly, the tensioning member being secured to the anvil head assembly to maintain the anvil head assembly in the first tilted position.

8. The anvil delivery system according to paragraph 7, wherein the head assembly defines first openings and the tensioning member includes a first suture, the first suture extending through the first openings and into an opening in the flexible tube.

9. The anvil assembly delivery system according to paragraph 3, wherein the anvil head assembly is pivotal from the operative non-tilted position, to a second tilted position which is different than the first tilted position.

10. The anvil assembly delivery system according to paragraph 9, wherein the anvil assembly further comprises a rotatable cam member and a plunger, the plunger being spring biased into contact with the cam member and movable distally to rotate the cam member to effect movement of the anvil head assembly from the first tilted position to the operative non-tilted position.

11. The anvil delivery system according to paragraph 10, wherein the cam member is rotatable and the plunger is movable distally to move the anvil head assembly from the operative tilted position to a second tilted position different than the first tilted position.

12. The anvil delivery system according to paragraph 1, further comprising an adapter connecting the anvil assembly to the second end of the flexible tube.

13. The anvil delivery system according to paragraph 2, wherein the suture tube has a length to extend from anvil assembly to a position extending from a patient's mouth during an anvil delivery procedure.

Claims

1. An anvil assembly delivery system comprising:

   an anvil assembly including a center rod and an anvil head assembly secured to the center rod;
   a flexible tube having a first end configured for oral insertion into a patient and a second end, the anvil assembly being connected to the second end of the flexible tube;
   a retrieval suture connected to the head assembly, the retrieval suture being positioned to extend from the anvil assembly in a direction opposite to the flexible tube; and
   a spacer supported on the retrieval suture adjacent the anvil head assembly, the spacer being dimensioned to prevent the suture from being clamped between the anvil head assembly and a stapling instrument and becoming trapped in a staple line.

2. The anvil assembly delivery system according to claim 1, wherein the spacer includes a suture tube defining a suture channel, the suture channel receiving the retrieval suture and being positioned adjacent the anvil head assembly.

3. The anvil assembly delivery system according to claim 1 or claim 2, wherein the anvil head assembly is movable from a first tilted position to a non-tilted operative position.

4. The anvil assembly delivery system according to claim 2 or claim 3, wherein the suture tube has an outer diameter of between 0.0625 inches and 0.50 inches.

5. The anvil assembly delivery system according to claim 4, wherein the suture tube has an outer diameter of between 00.625 inches and 0.25 inches.

6. The anvil delivery system according to claim 4, wherein the suture tube has an outer diameter of .25 inches.

7. The anvil assembly delivery system according to claim 3, further including a tensioning member connected to the anvil head assembly, the tensioning member being secured to the anvil head assembly to maintain the anvil head assembly in the first tilted position.

8. The anvil delivery system according to claim 7, wherein the head assembly defines first openings and the tensioning member includes a first suture, the first suture extending through the first openings and into an opening in the flexible tube.

9. The anvil assembly delivery system according to any of claims 3 to 8, wherein the anvil head assembly is pivotal from the operative non-tilted position, to a second tilted position which is different than the first tilted position.

10. The anvil assembly delivery system according to claim 9, wherein the anvil assembly further comprises a rotatable cam member and a plunger, the plunger being spring biased into contact with the cam member and movable distally to rotate the cam member to effect movement of the anvil head assembly from the first tilted position to the operative non-tilted position.

11. The anvil delivery system according to claim 10, wherein the cam member is rotatable and the plunger is movable distally to move the anvil head assembly from the operative tilted position to a second tilted position different than the first tilted position.

12. The anvil delivery system according to any preceding claim, further comprising an adapter connecting the anvil assembly to the second end of the flexible tube.

13. The anvil delivery system according to any of claims 2 to 12, wherein the suture tube has a length to extend from anvil assembly to a position extending from a patient's mouth during an anvil delivery procedure.

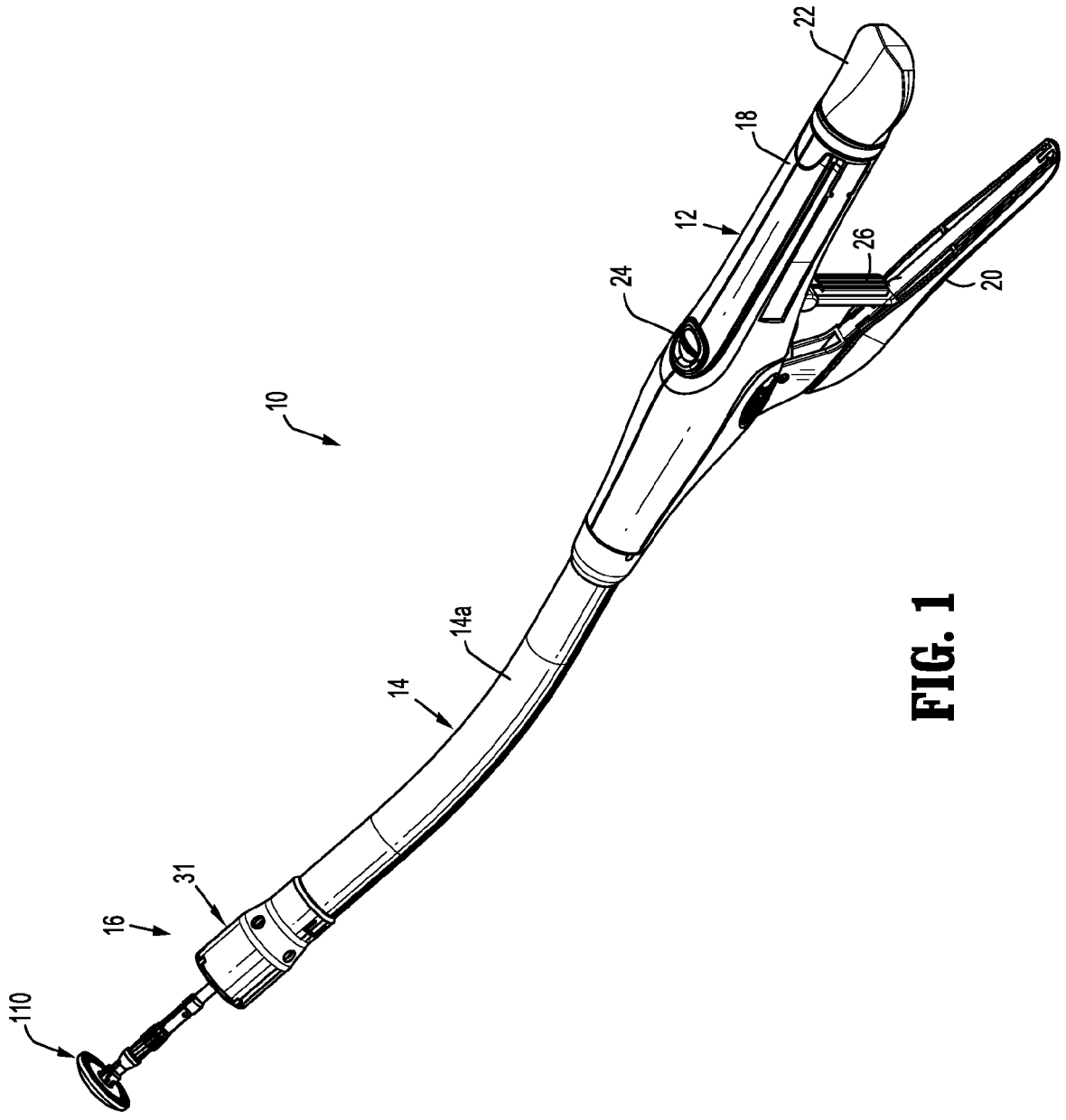
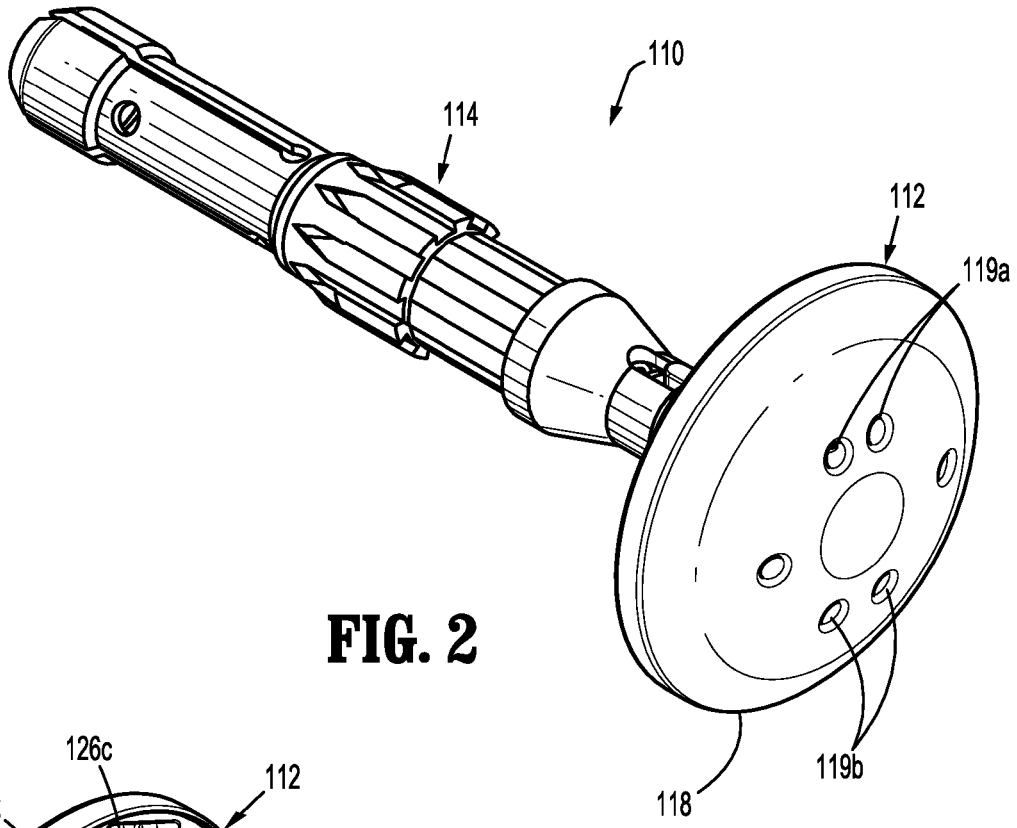


FIG. 1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118

FIG. 2

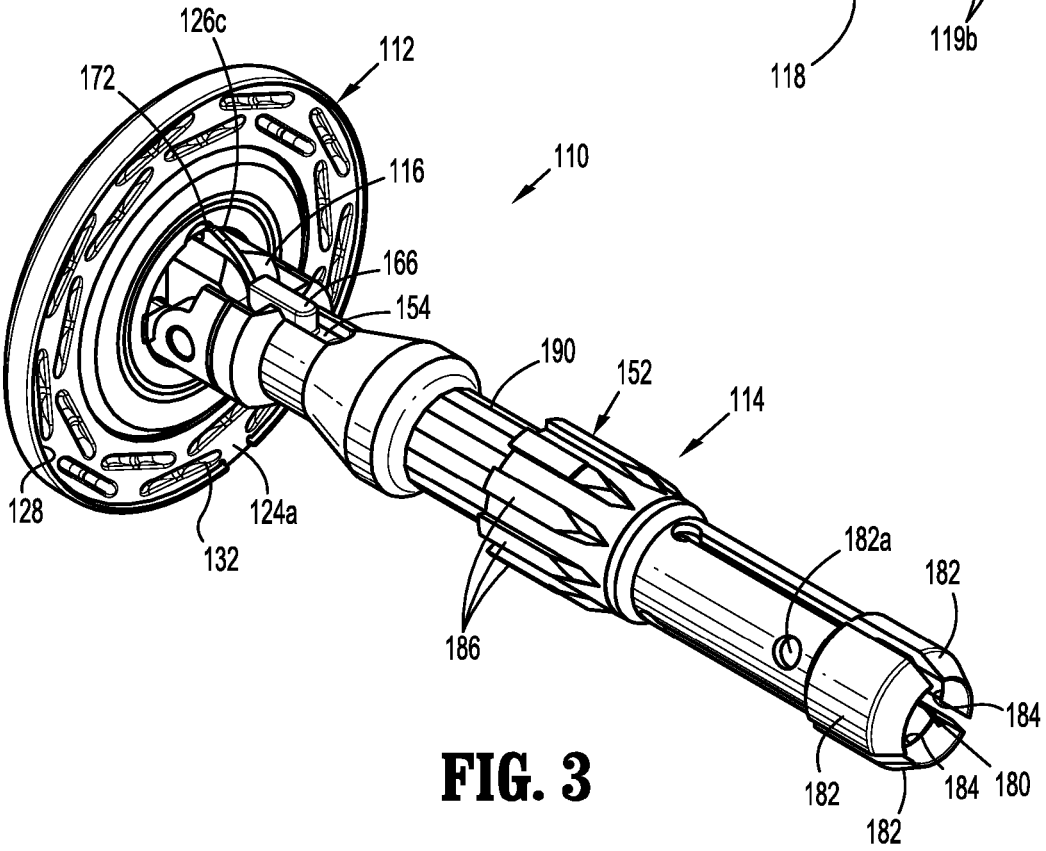
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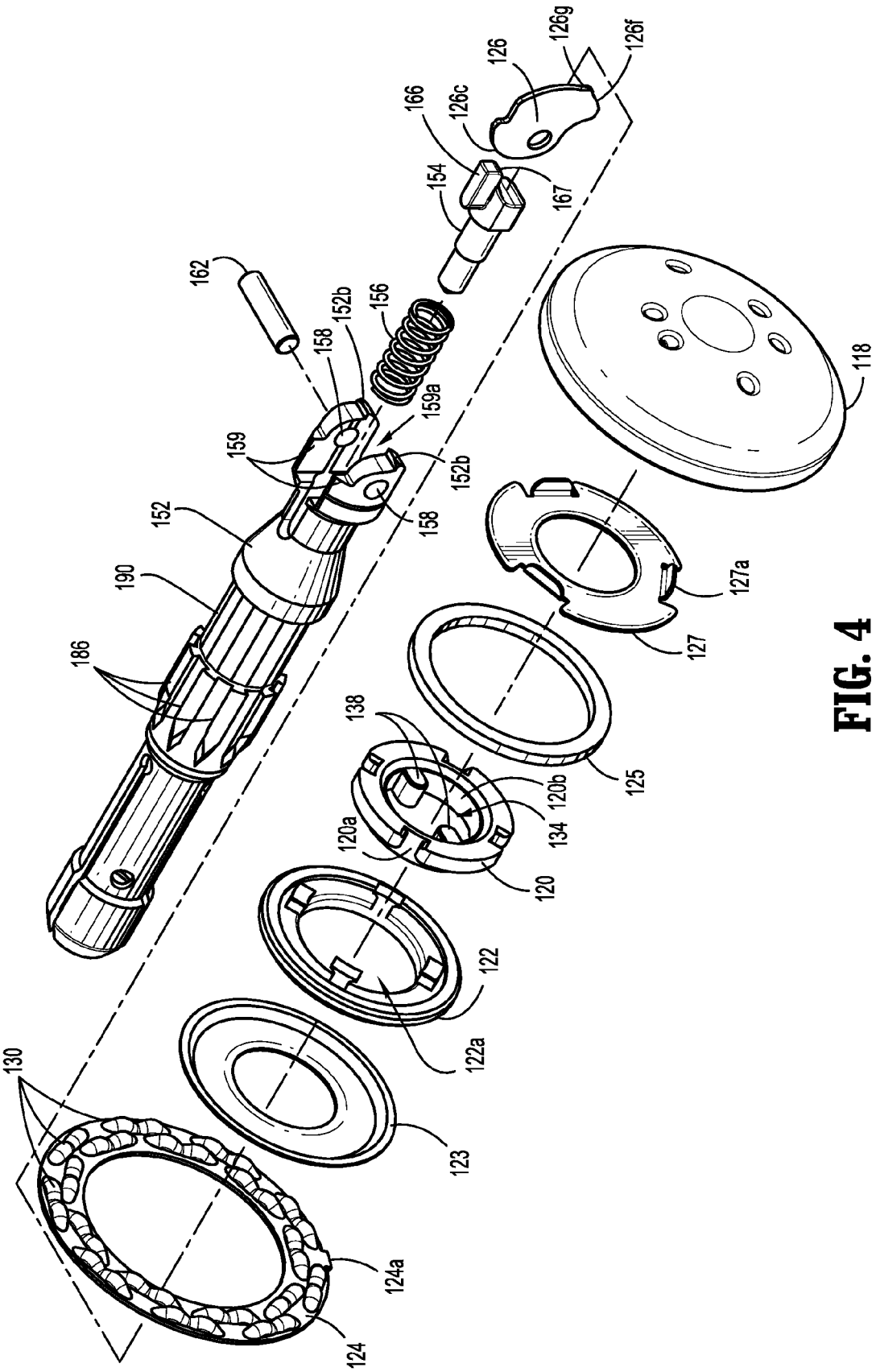
FIG. 3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124

FIG. 4

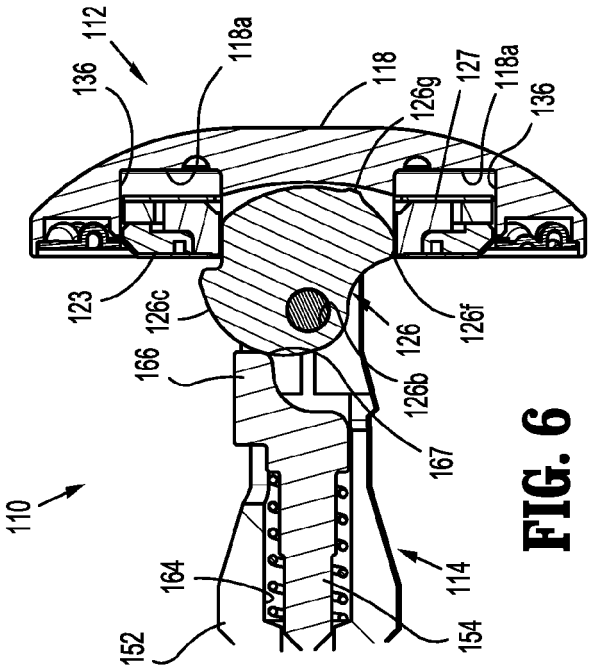


FIG. 6

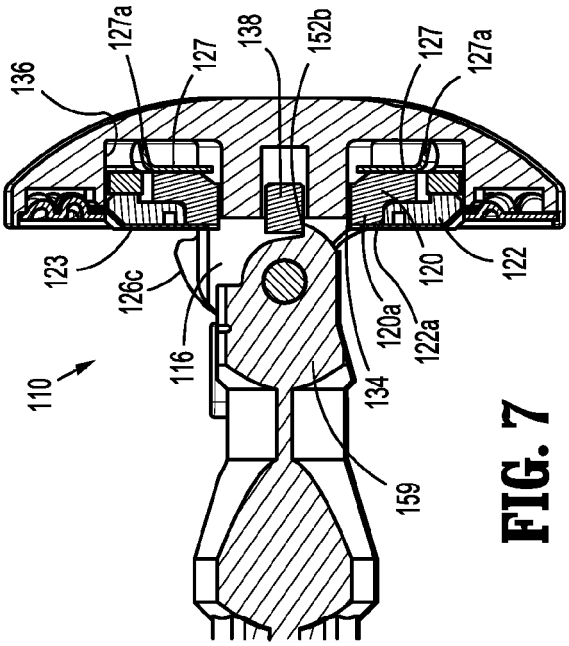


FIG. 7

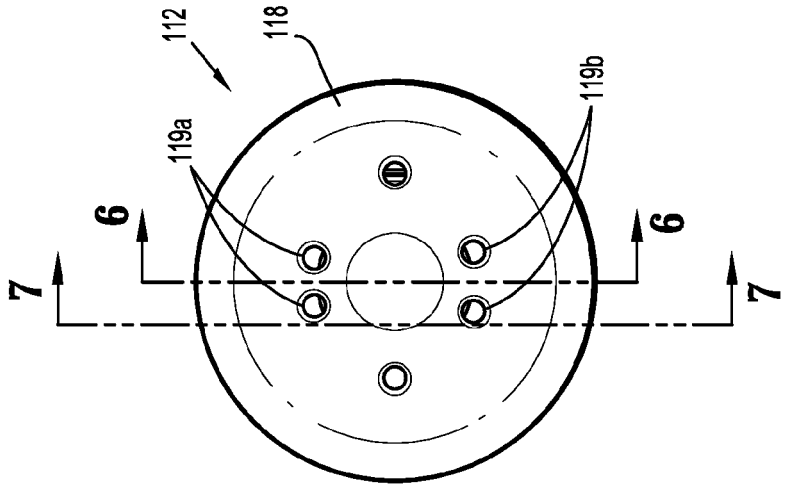
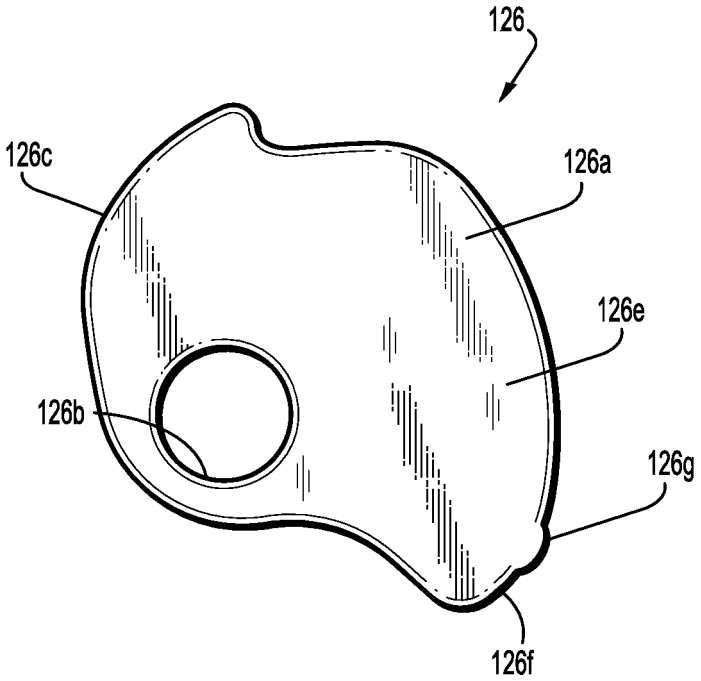


FIG. 5



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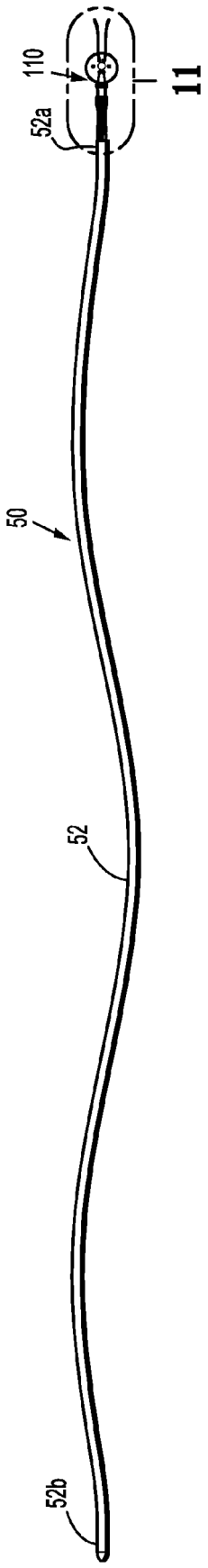
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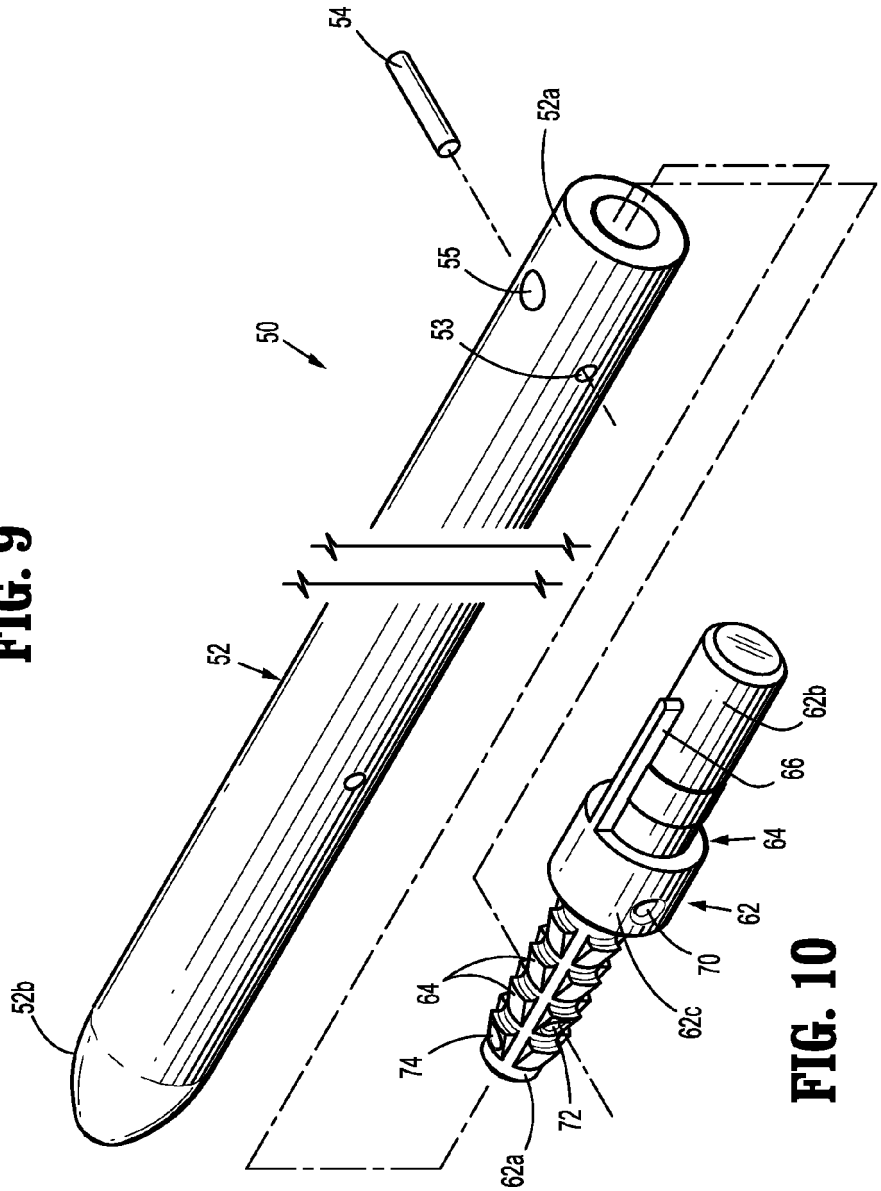
FIG. 9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62c
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62a

FIG. 10

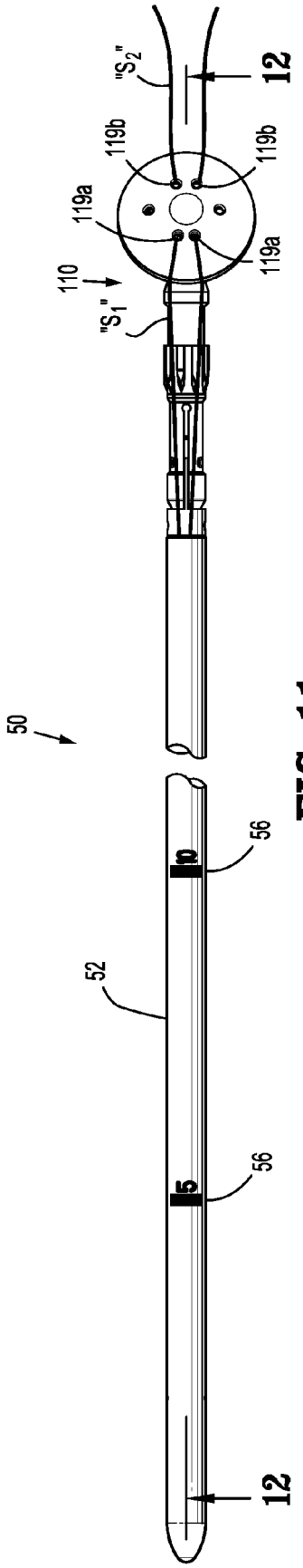
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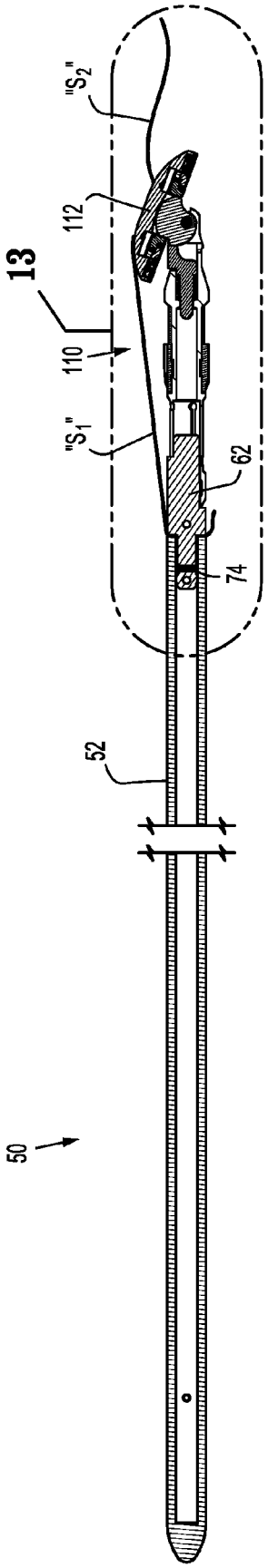
FIG. 11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"S1"
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74
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50

FIG. 12

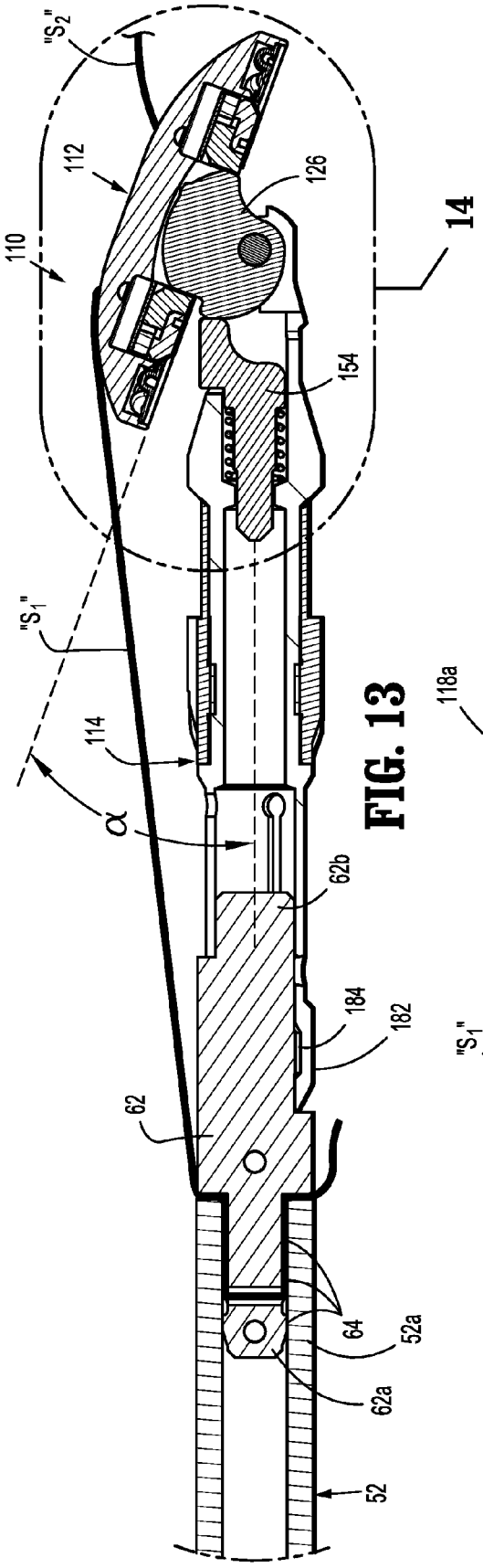
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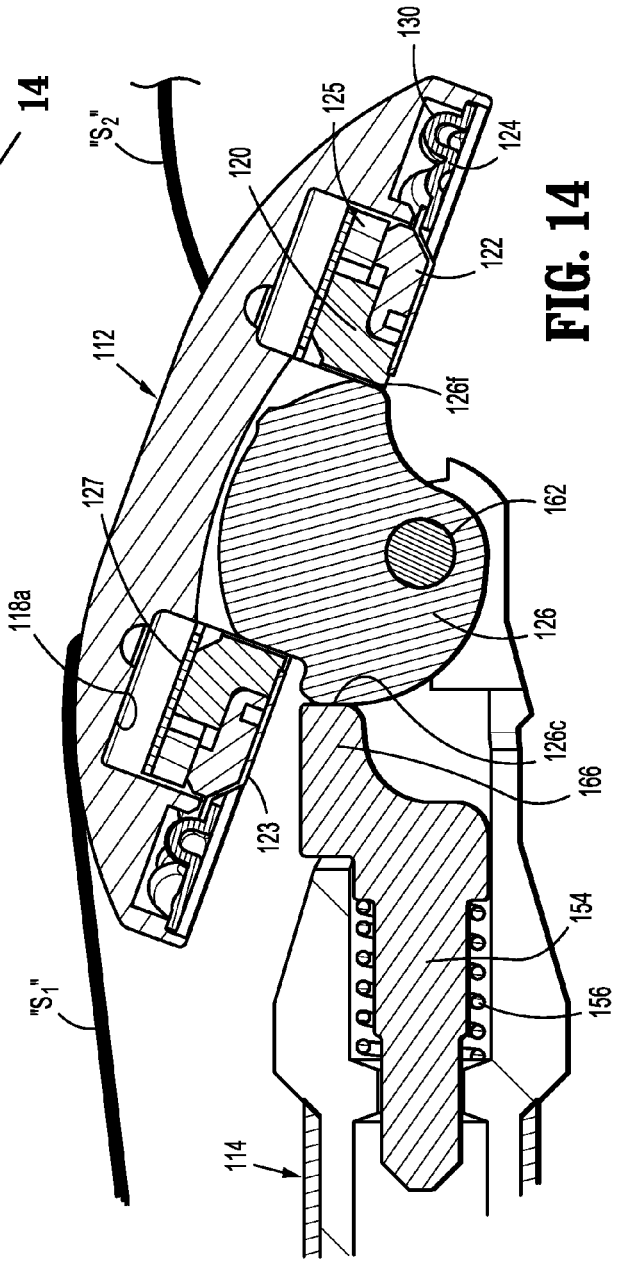
FIG. 13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"S1"
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FIG. 14

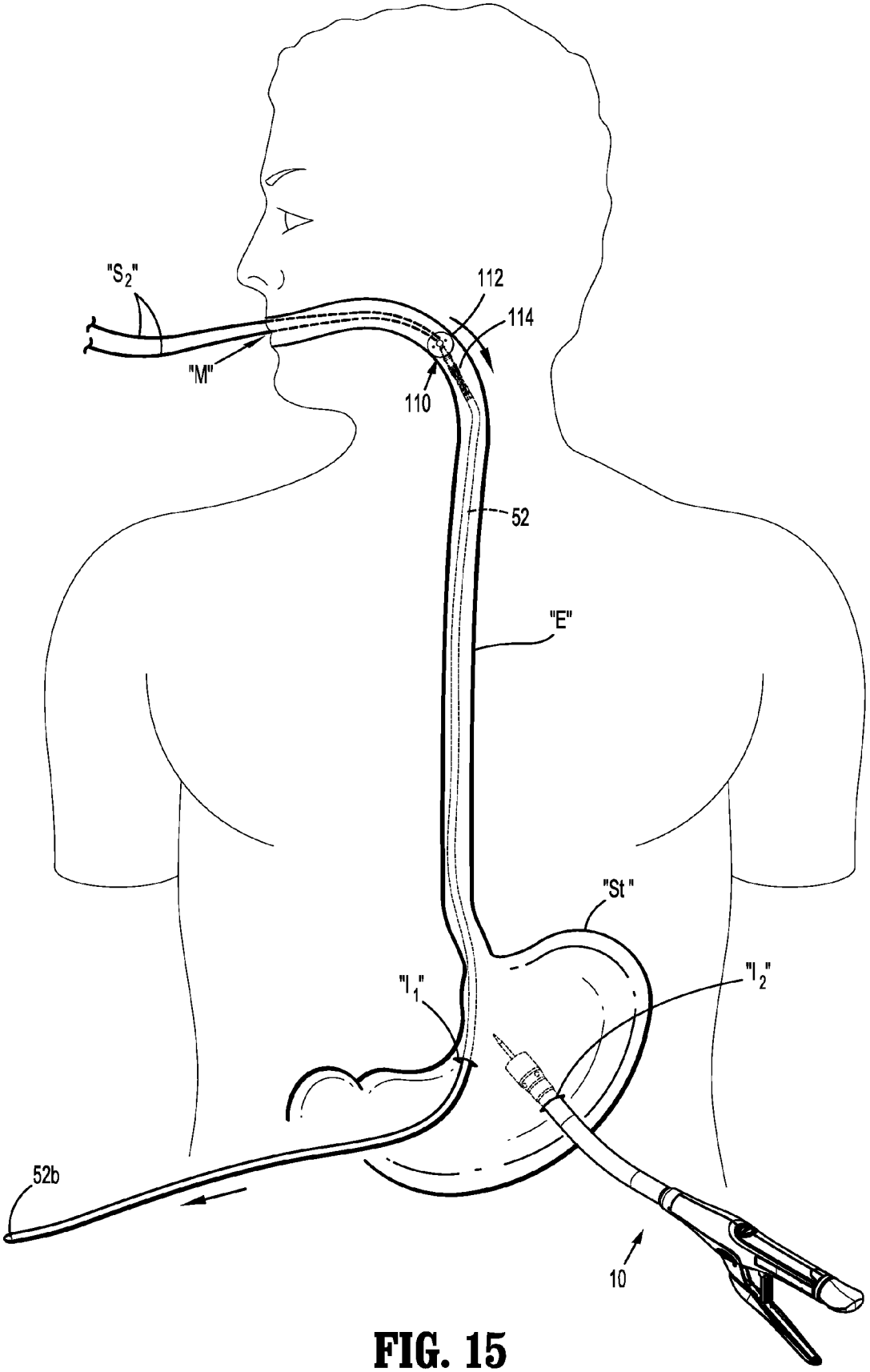

FIG. 15

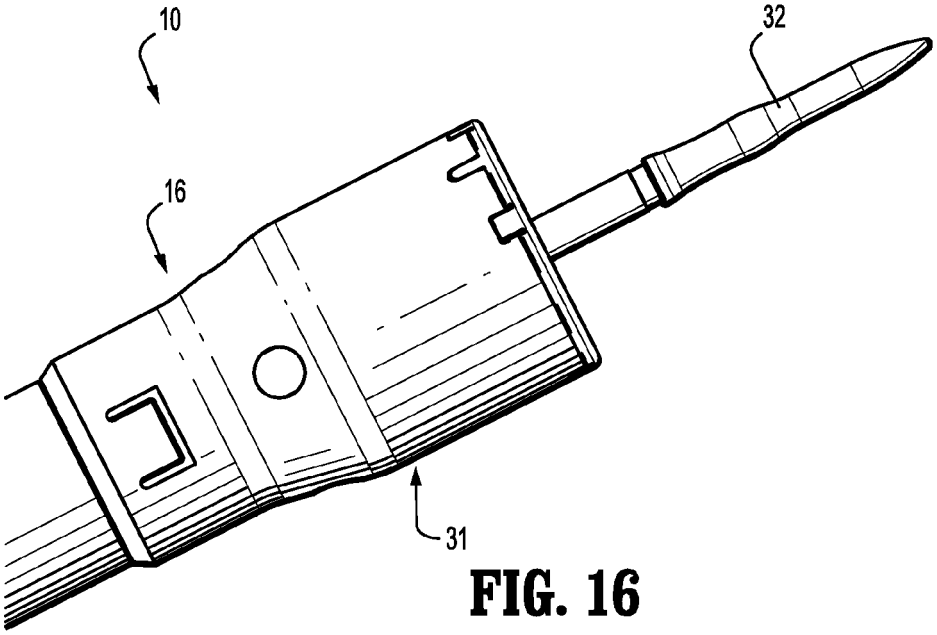

FIG. 16

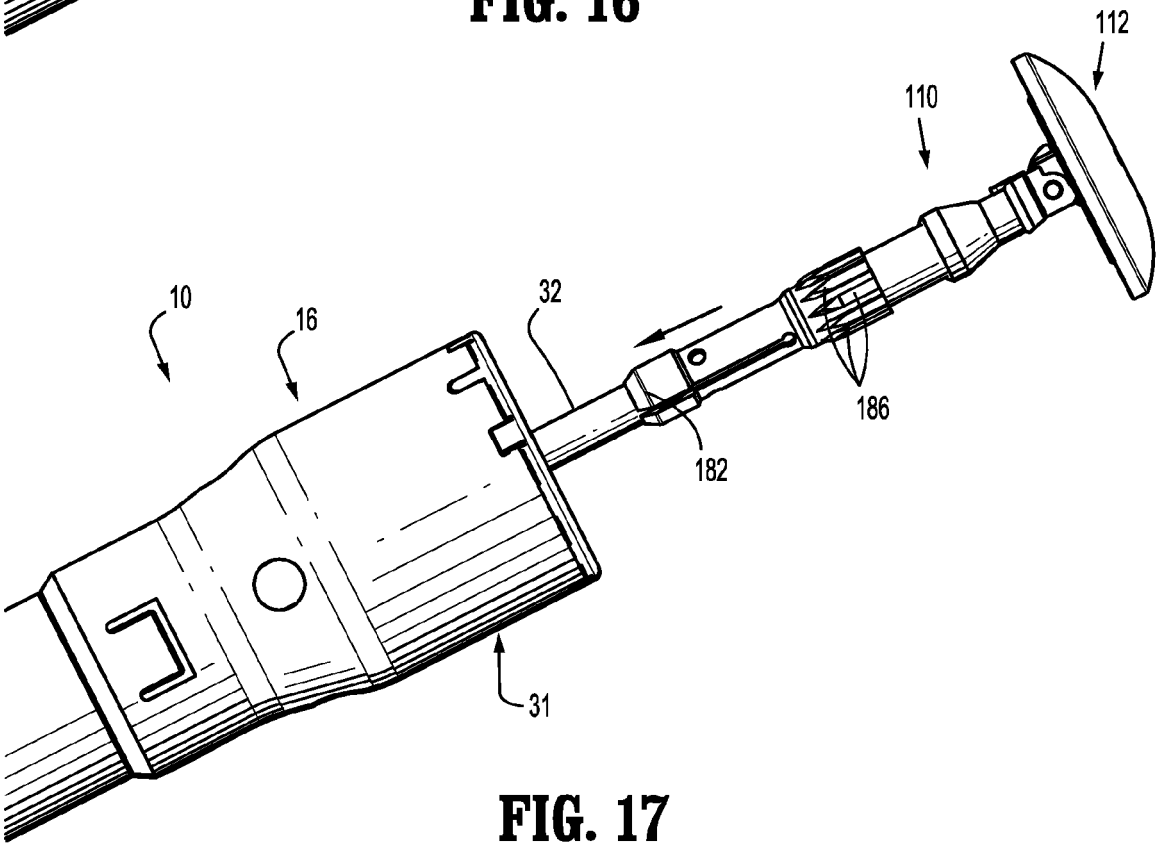

FIG. 17

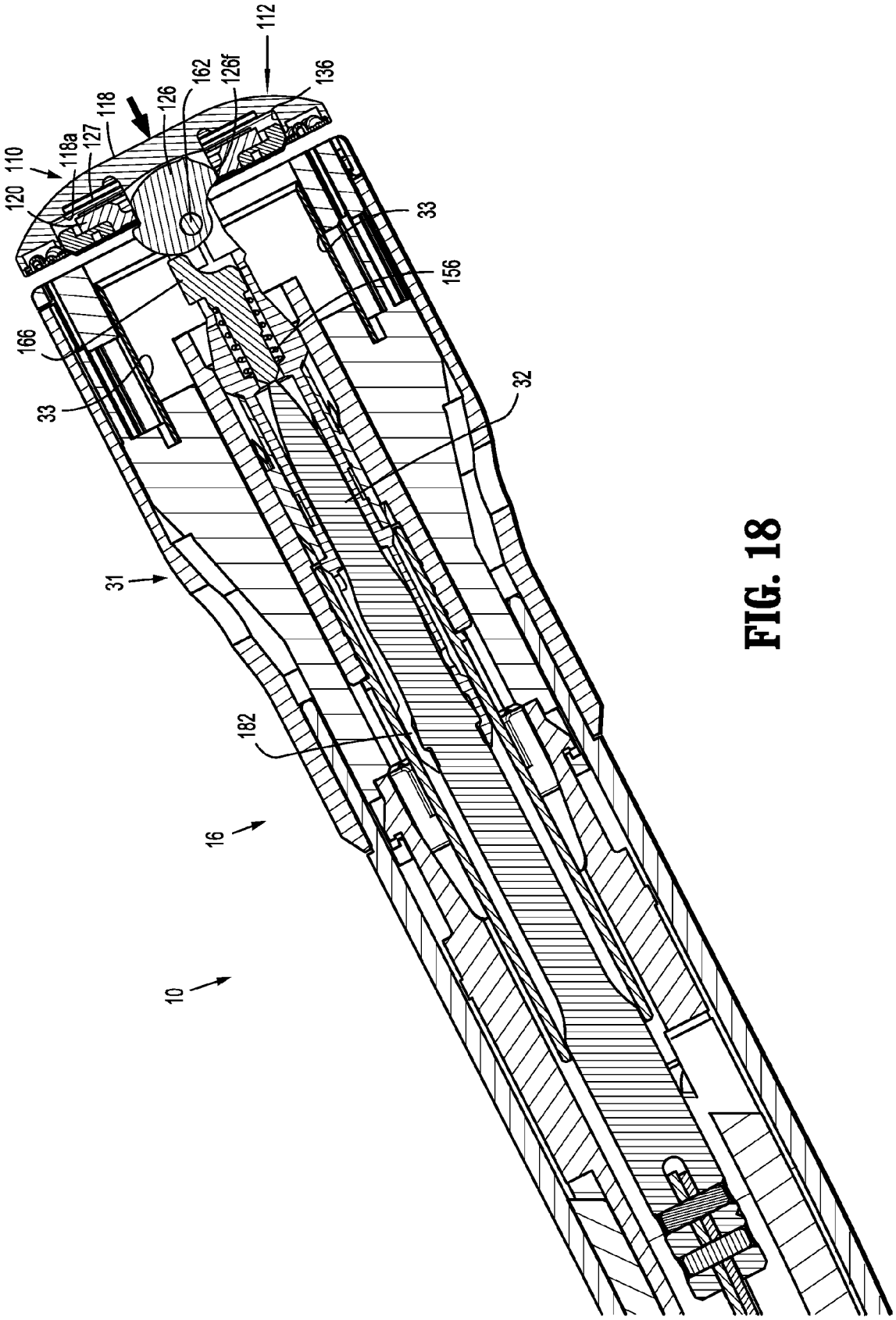
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FIG. 18

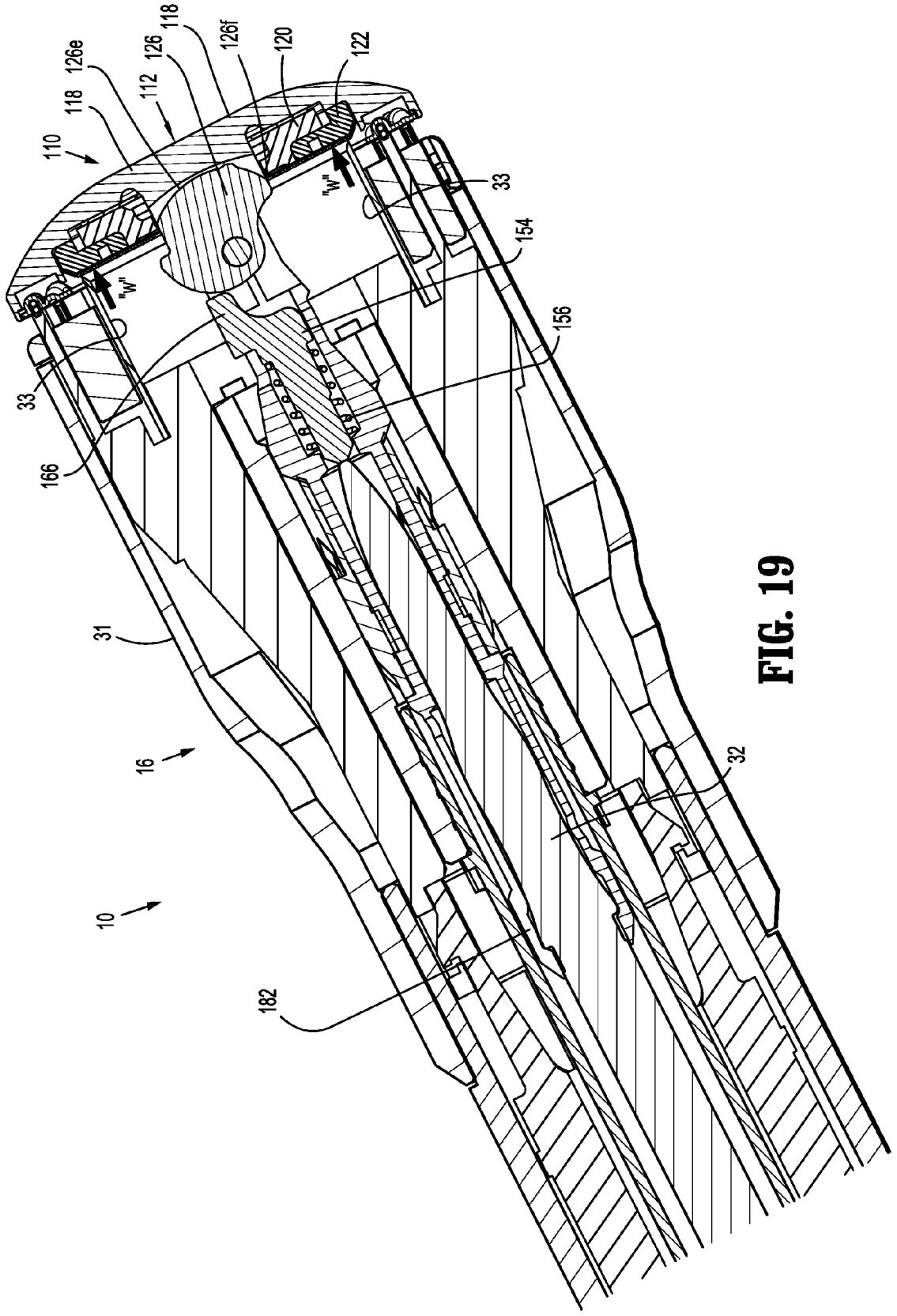
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FIG. 19

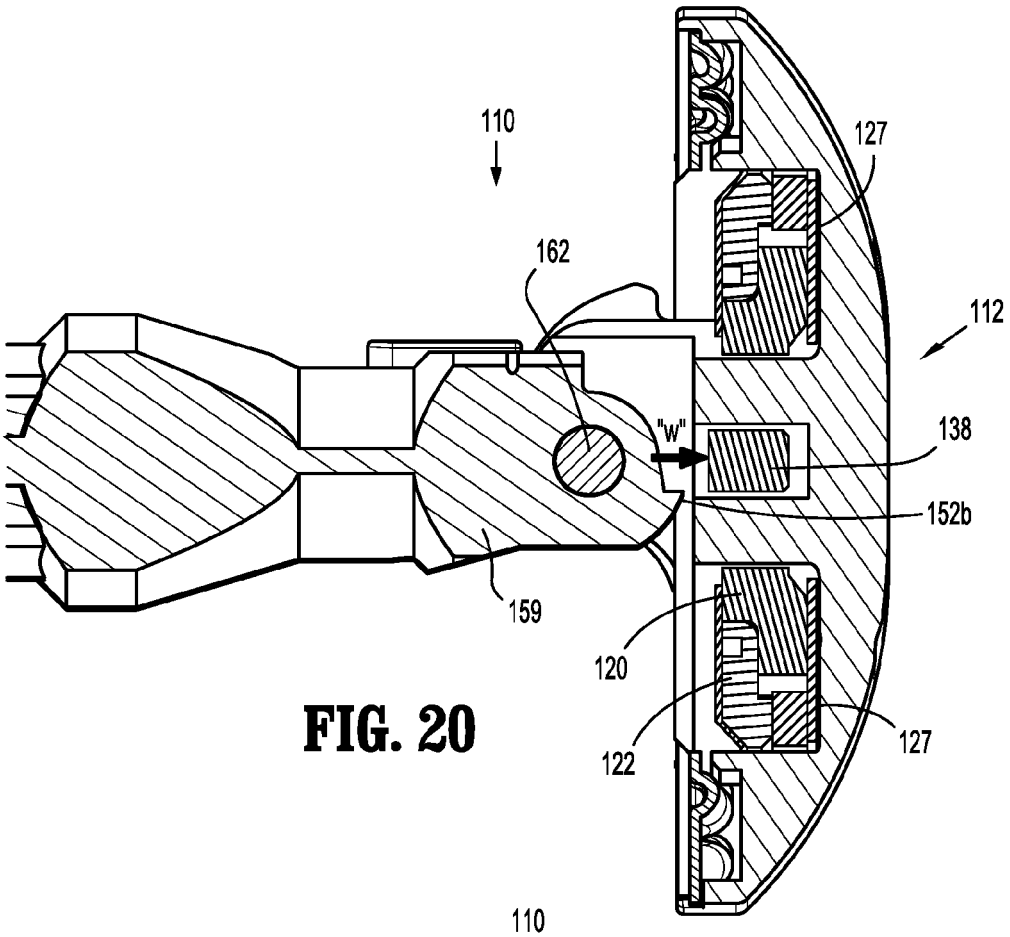
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FIG. 20

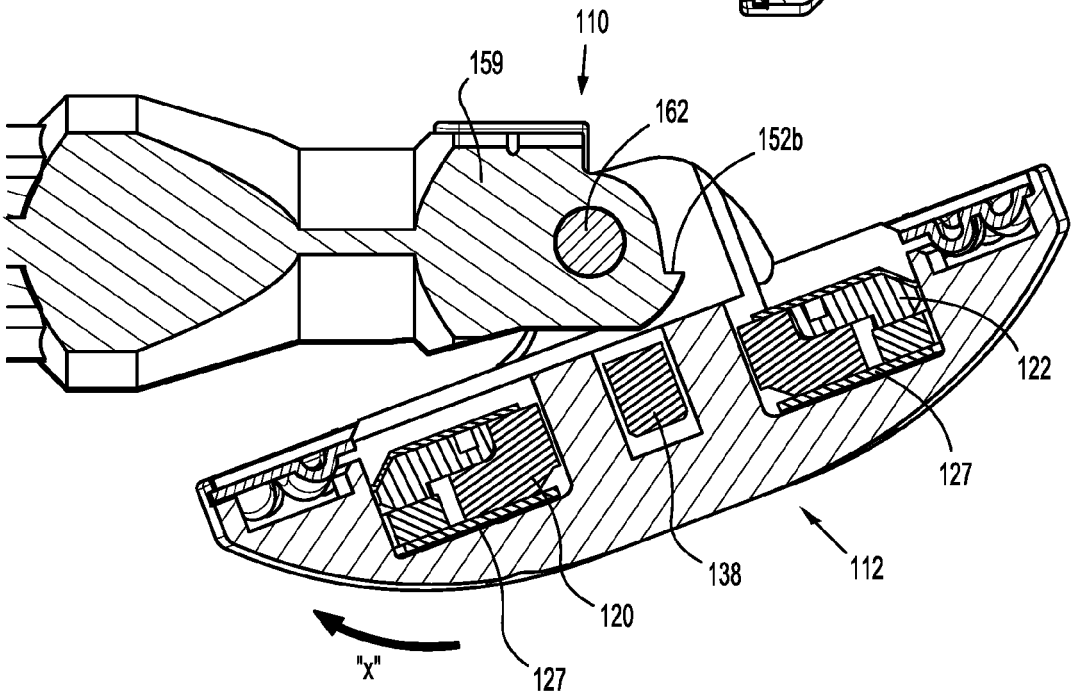
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FIG. 21

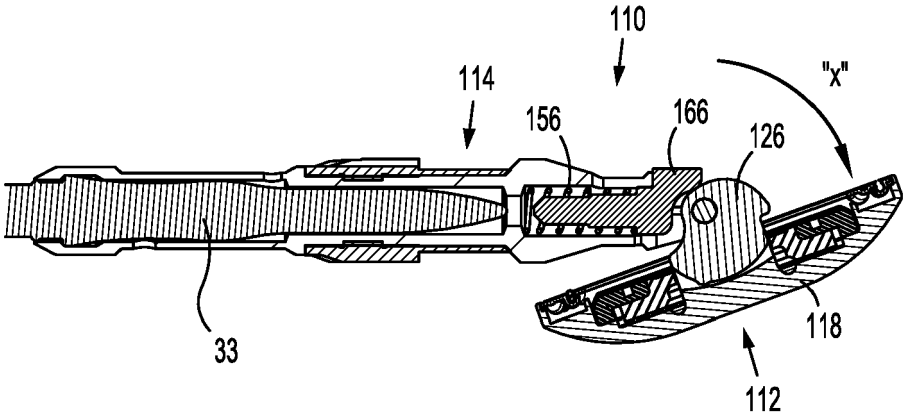

FIG. 22

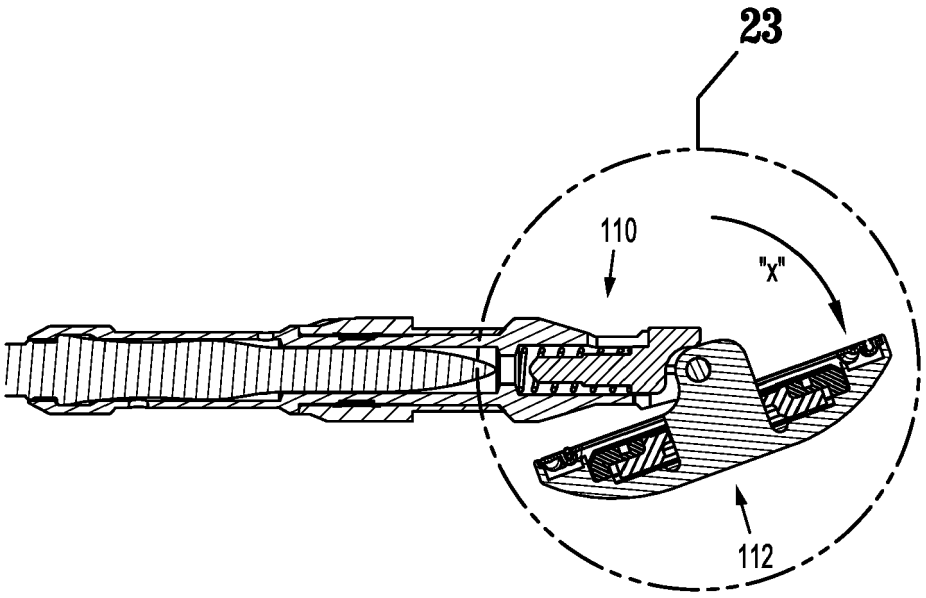

FIG. 22A

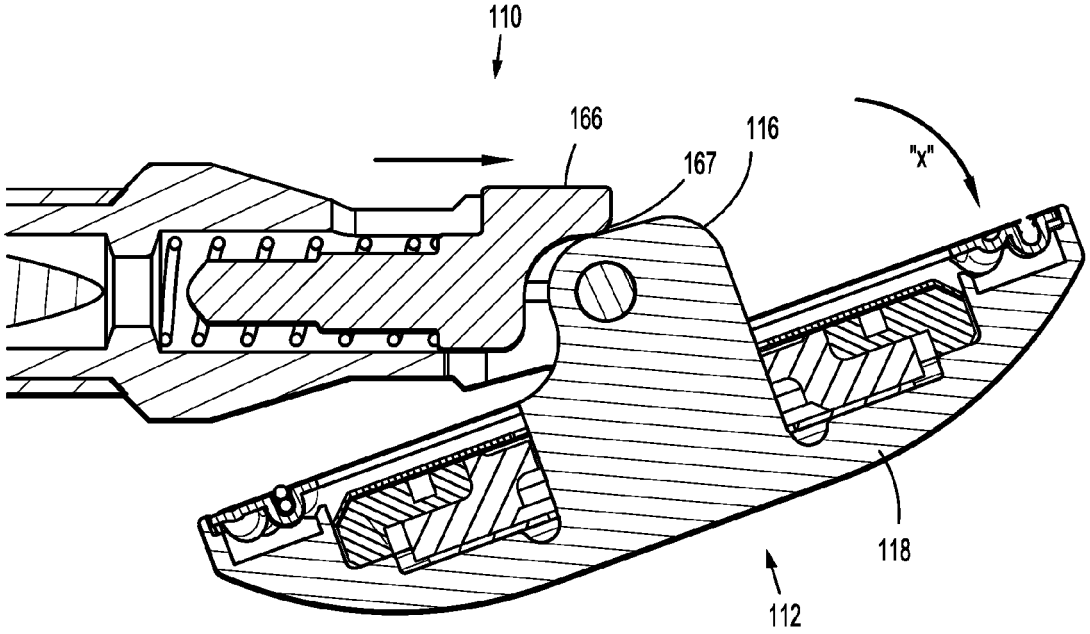

FIG. 23

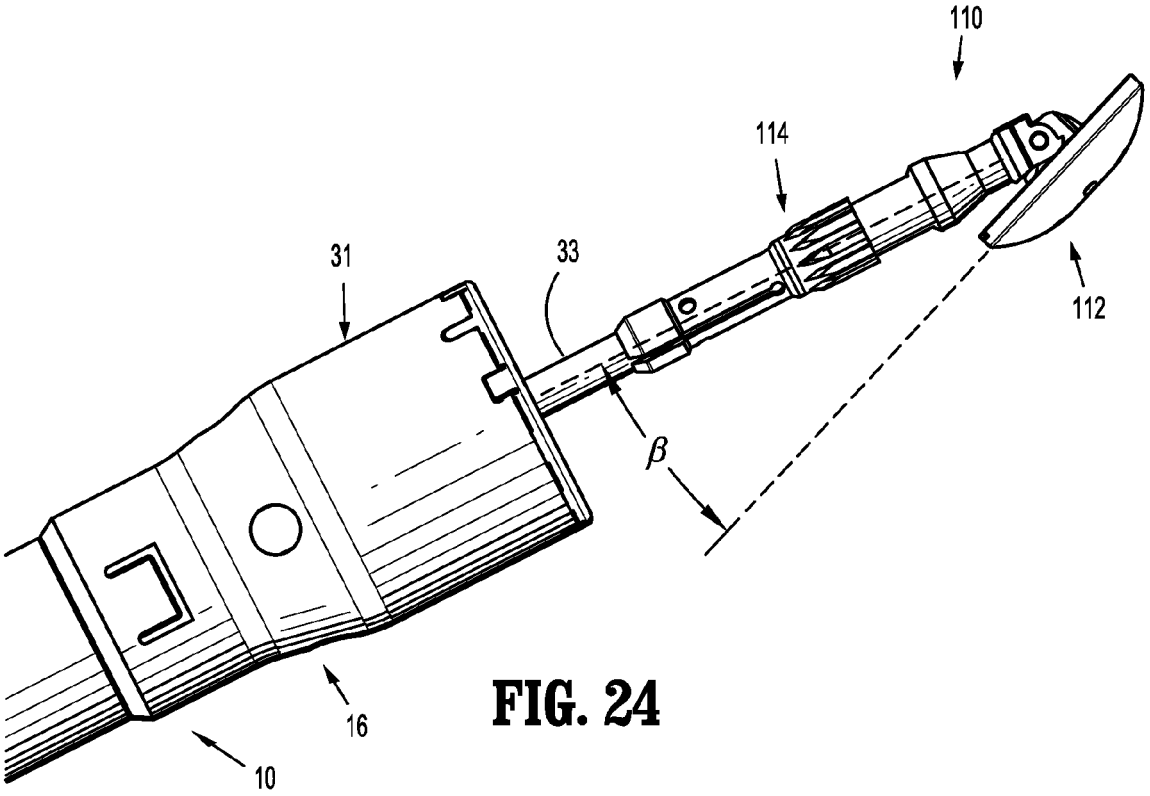

FIG. 24

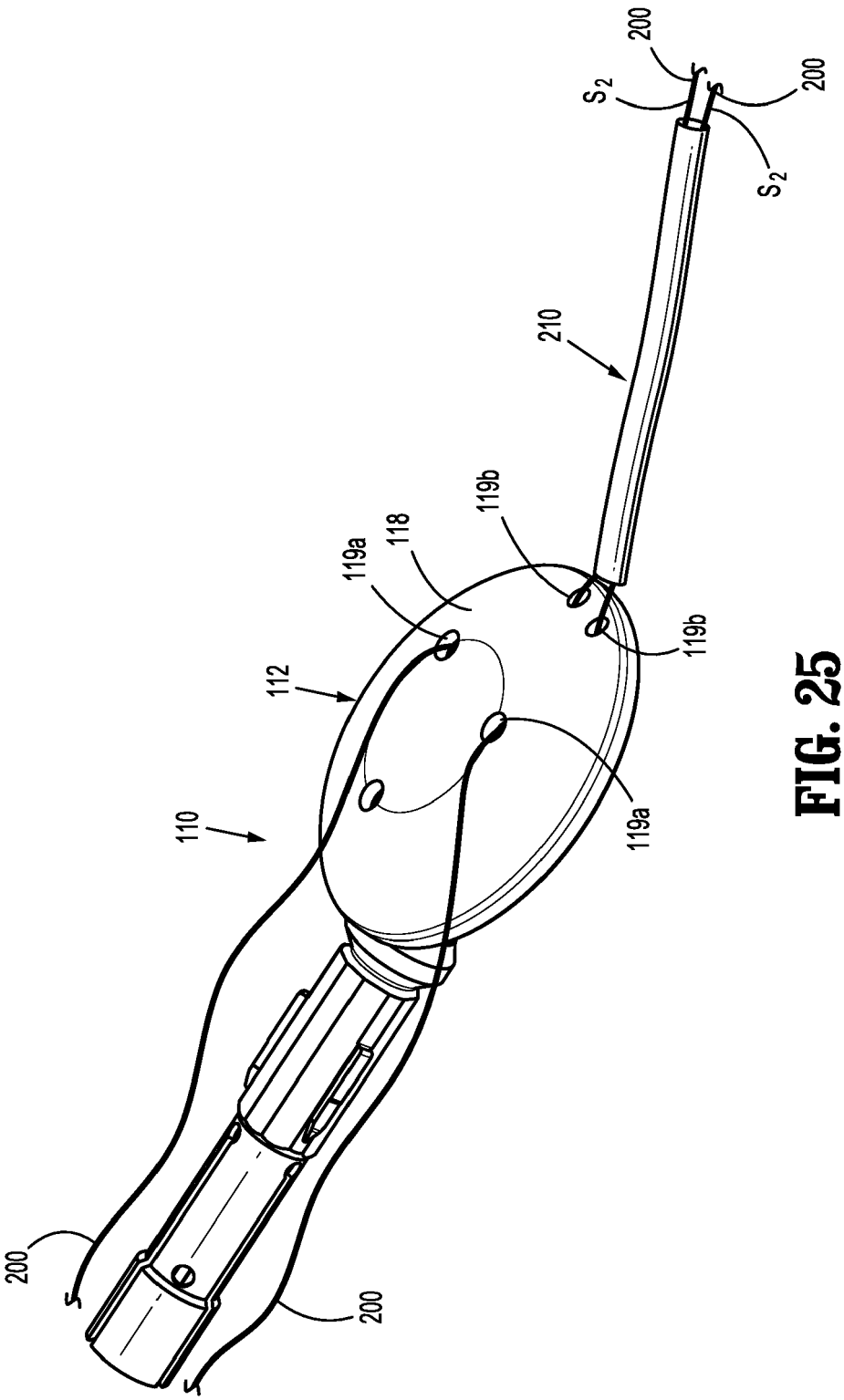

FIG. 25

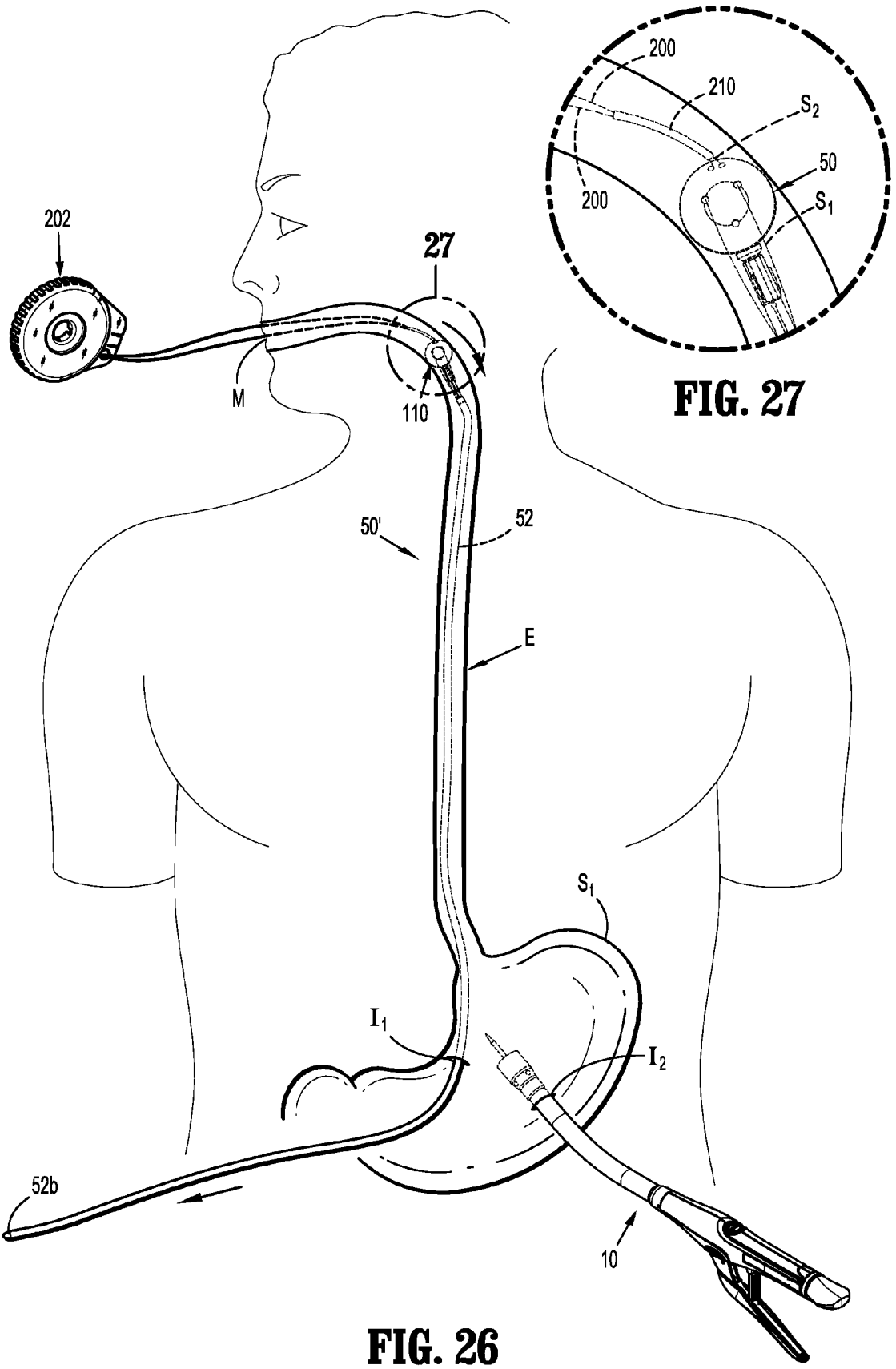

FIG. 27

FIG. 26

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European Patent Office
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EUROPEAN SEARCH REPORT

Application Number
EP 15 17 3257

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
A	EP 2 153 781 A2 (TYCO HEALTHCARE [US]) 17 February 2010 (2010-02-17) * the whole document * -----	1-13	INV. A61B17/115
A	US 2006/229643 A1 (NOLAN TIM [US] ET AL) 12 October 2006 (2006-10-12) * paragraph [0099] - paragraph [0103] * * figures 40-44 * -----	1	
A	EP 2 039 303 A2 (TYCO HEALTHCARE [US]) 25 March 2009 (2009-03-25) * paragraph [0031] - paragraph [0035] * * figures 1-5 * -----	1	
			TECHNICAL FIELDS SEARCHED (IPC) A61B

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
Munich	16 September 2015	Ebbinghaus, M

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16-09-2015

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